Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

* *

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File 2:12-MD-02327
MDI No. 2327

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THIS DOCUMENT RELATES TO ALL WAVE 4 PLAINTIFFS

Joseph R. Goodwin
U.S. District Judge

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Courtyard Marriott
4300 E. Empire Place
March 17, 2017
8:30 a.m.
Sioux Falls, South Dakota

* *

D E P O S I T I O N O F

Michael Fiegen, M.D.

* *

APPEARANCES:

Mr. Nate Jones (via telephone)
Wagstaff & Cartmell, LLP
4740 Grand Avenue, Suite 300
Kansas City, Missouri 64112

for the Plaintiffs;

Mr. Barry J. Koopmann
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Minneapolis, Minnesota 55402

for the Defendants.

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S T I P U L A T I O N

It is stipulated and agreed, by and between the above-named parties through their

attorneys of record, whose appearances have been hereinabove noted, that the deposition of MICHAEL FIEGEN, M.D., may be taken at this time and place, that is, at the Courtyard Marriott, Sioux Falls, South Dakota, on the 17th day of March, 2017, commencing at the hour of 8:30 a.m.; said deposition taken before Pat L. Beck, Registered Merit Reporter and Notary Public within and for the States of South Dakota and Minnesota; said deposition taken for the purpose of discovery or for use at trial or for each of said purposes, and said deposition is taken in accordance with the applicable Rules of Civil Procedure as if taken pursuant to written notice. Objections, except as to the form of the question, are reserved until the time of trial. Insofar as counsel are concerned, the reading and the signing of the transcript by the witness is waived.

MICHAEL FIEGEN, M.D.,

called as a witness, being first duly sworn, deposed and said as follows:

EXAMINATION BY MR. JONES:

Q Hi, Doctor. My name is Nate Jones. I'm an

attorney that represents the Plaintiffs in this litigation. Do you understand that this is my opportunity to ask you questions about the opinions that you have rendered in this litigation?

A Yes. Yes, I do.

Q Could you state your name just for the record, please.
A Michael M. Fiegen.
Q And, Dr. Fiegen, have you ever acted as an expert witness before?
A I have.
Q Have you acted as an expert witness in any transvaginal mesh cases before?
A No, I -- no. No, I have not. I had my deposition taken regarding a single patient.
Q Tell me more about your deposition taken regarding a single patient.
A I was asked by a colleague to evaluate a patient who was having mesh-related complications. I saw her. I offered her my thoughts and my recommendation, and that was the extent of my involvement with that patient.

I was subsequently -- when she filed suit against Johnson & Johnson, I was subsequently asked to provide deposition testimony regarding her -- my

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involvement with her.
Q Were you a treating physician of this patient?
A No. I was simply a consultant.
Q What mesh -- what Ethicon mesh product was implanted inside of this patient?
A The ProLift mesh.
Q And in your consultation work did you form any opinions related to this patient's mesh-related

complications?
A I did.
Q And what were those opinions?
A I felt that the patient had an allergic response to the prolene mesh and that that was why, despite having removed an overwhelming majority of the material, that she continued to experience discomfort and pain.
Q Did you perform the removal surgery?
A No.
Q You formed an opinion with a patient that a patient suffered from an allergic response to the prolene mesh used by Ethicon?
A That was my opinion.
Q And what did you base that opinion on?
A My medical experience.
Q And you gave a deposition related to that

patient; correct?
A I did.
Q And do you recall the name of that lawsuit?
A I'm not sure. Are lawsuits named?
Q Yes.
A I remember the patient but that's the extent of what I recall.
Q Okay. What was the patient's name?
A I believe her last name was Gross.
Q Okay. The patient's name wasn't Linda Gross,

was it?
A Yes, I believe it was.
Q And are you aware of whether or not that case proceeded to trial?
A My understanding is that it did proceed to trial.
Q And are you aware whether or not a verdict was rendered in that case?
A I was made aware -- or I was told that a Plaintiff's verdict was rendered.
Q Have you performed any transvaginal mesh removal surgeries, Dr. Fiegen?
A Can I ask you to specifically designate that as either pelvic organ prolapse mesh or midurethral -- or sling procedures?

Q Sure. First, I'll ask you: Dr. Fiegen, have you removed any transvaginal mesh products used to treat stress urinary incontinence?
A Yes, I have.
Q Have you removed transvaginal mesh products used to treat stress urinary incontinence manufactured by Ethicon?
A Yes, I have.
Q And have you removed TVT retropubic mesh products from patients?
A No, I have not.
Q Have you removed TVT obturator mesh products from patients?

A Yes, I have.
Q Have you also removed transvaginal mesh to treat pelvic organ prolapse from patients?
A Yes, I have.
Q How many total removal surgeries have you performed related to transvaginal mesh to treat stress urinary incontinence?
A I've removed three.
Q How many removal surgeries of transvaginal mesh products to treat pelvic organ prolapse have you performed?
A Two.

Q Of the three removal surgeries you have performed related to transvaginal mesh to treat stress urinary incontinence, how many of those removal surgeries involved the TVT obturator product?
A All three.
Q Okay. And the three removal surgeries of the TVT obturator mesh you performed, did you implant the TVT obturator mesh product in those patients?
A I implanted two of the three.
Q What were the two pelvic organ prolapse transvaginal mesh products you removed from patients?
A They were both transobturator mesh products.
Q And do you know the pelvic organ prolapse

transvaginal mesh products that you removed from patients?

A I'm sorry. I misunderstood your last question.

Q Let me go back and ask you again.

A All righty.

Q The two transvaginal mesh products for the treatment of pelvic organ prolapse that you removed from patients, are you aware of what company made those products?

A Yes. Both of them were AMS products.

Q Okay. And what were the names of those products?

A I don't recall.

Q And did you implant those two AMS transvaginal mesh products?

A Yes, I did.

Q The three removal surgeries that you performed related to the TVT obturator mesh, why did you perform those surgeries?

A All three of the patients were reporting pain, and they first were treated medically with anti-inflammatory medications, with mild narcotics. And all three of them, prior to removal of their mesh, were treated with trigger point injections with Lidocaine, or Marcaine, and Triamcinolone.

Q Did you believe that removal of the TVT obturator mesh from these patients would alleviate the patient's pain?

A That was our hope going into the surgery.
Q And had you made a determination in those three patients' cases that the TVT obturator mesh was causing these patients pain?
A No. The pain was -- seemed more related to, again, a type of allergic-type response with both -- both of the patients that I had taken care of, and

had placed the mesh, and, again, the surgical intervention certainly can cause pain, can cause dyspareunia for some patients, but it simply was associated with the surgical intervention. I had no reason to believe that the TVT itself was what was causing her -- the patient's pain.
Q Doctor, do you hold the opinion that transvaginal mesh cannot cause pain in a woman?
A I believe that any -- any vaginal surgery that we do, any surgical intervention, no matter what it is, can lead to pain for patients.
Q Fair to say that you hold the opinion that the presence of transvaginal mesh inside of a patient's body can cause that patient pain in some cases?
MR. KOOPMANN: Object to form.
THE WITNESS: Answer?
MR. KOOPMANN: Yeah.
A Sorry. Again, what I believe is that any surgical intervention, in whatever area of the body, and particularly as it relates to pelvic surgery,

any surgery can cause pain for these patients.

Q (By Mr. Jones) Okay. And I'm not asking about any surgery. I'm asking specifically about the presence of mesh. So I'm going to ask you again.

Doctor, do you believe that the presence

of transvaginal mesh inside of a woman's vagina can cause that woman pain?

A Again, I have to reiterate, there are many vaginal procedures that we do. Some of them can cause persistent pain for patients, and all of them can, and so I believe that that's the appropriate answer in this circumstance.

Q Well, I'm not asking you about any surgeries. Okay. So I want to get an answer to whether you believe pain can be caused by the presence of mesh inside of a woman's vagina. I am not asking about any other surgery except for -- and I'm not actually asking about surgery at all. So here's the question. Let's see if I can get you to answer it.

Do you believe the presence of transvaginal mesh, the mere presence of transvaginal mesh inside of a patient's vagina, can cause that patient pain?

MR. KOOPMANN: Object to form. You can answer.

A Patients that have any kind of pelvic surgery, whether it's transvaginal mesh, whether it's an anterior or a posterior repair, whether it's a sacral colpopexy can have pain postoperatively.

Typically pain is mediated by the presence of prostaglandins that are released from tissue that

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is disrupted in the course of the procedure, and I don't really know any other way to answer that. It's the surgical intervention and the release of prostaglandins and many other chemical mediators that lead to pain.

Q (By Mr. Jones) Doctor, have you ever acted as a consultant for any transvaginal mesh companies?

A I hope -- I will try to answer that correctly. I did teach a single physician early on, I believe it was 2004 or 2005, at the request of the Ethicon company. I taught that physician how to place retropubic midurethral slings.

Q Is that something that Ethicon asked you to do?

A The Ethicon representative in our area asked me to do that.

Q Do you practice with a Dr. Benson?

A I do.

Q Do you know whether or not Dr. Benson has acted as a consultant for any transvaginal mesh company?

A I don't know that for sure. I'm not aware of any mesh-producing companies that Dr. Benson has been directly involved with as their consultant.

Q Has Ethicon paid your expenses to travel to any events?

A No, they have not.

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Q Has Ethicon ever sponsored any marketing events related to your practice?
A I'm not certain that I can answer that correctly. My partner and I, three or four years ago, had a public event that we talked about this area of female medicine, and I cannot recall whether or not Ethicon was a contributing sponsor to that event. It was called Sisterhood something, and it was a group that helped to coordinate the public -- or the public access to understanding this area of medicine.
Q Has Ethicon ever assisted you in holding any marketing events?
A Again, up until the last year or two, once a year, during Bladder Awareness Month, we would have a public engagement at one of our clinics. And, actually, I cannot recall that Ethicon at any time assisted in the sponsorship of that.
Q Have you attended any Ethicon training events?
A When I first learned -- when I was first introduced to the retropubic sling in the year 2000, I went to Cincinnati, and the Ethicon -- or the physician that was training me was sponsored by Ethicon.
Q Doctor, have you published any research related

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to transvaginal mesh products?
A No, I have not.
Q Doctor, have you ever performed any studies related to transvaginal mesh products?
A No, I have not.
Q Doctor, do you keep a patient registry of the patients that you have implanted transvaginal mesh products in?
A No, we do not.
Q Doctor, have you performed any research projects on transvaginal mesh devices?
A No, I have not.
Q Have you ever drafted Instructions For Use for transvaginal mesh products?
A No. No, I have not.
Q Have you ever been asked by any company to help draft Instructions For Use for any medical device?
A No. No, I have not.
Q Has Ethicon ever approached you to assist them in providing expertise in product development?
A In the earliest days of my utilization of the retropubic sling, the product representatives were very involved and asked to be able to attend the surgeries that we were doing. And if I recall, they tried to be present for the first 50 surgeries. And

after each surgery they would ask for my

recommendations, asked for my impressions of how the case went, asked me if I encountered any specific problems, and asked whether or not I thought that there would be an area that, if I could change, and impact the continued development of their procedure or their product, that they would -- they would be happy to hear about that and be able to transfer that information to their company representatives.

Q And did you offer any comments regarding developments to the TVT retropubic device to Ethicon sales representatives?

A Yes. You know, we talked about the trocars that were being used, and we talked about the tensioning of the midurethral sling and how that could be most effectively established in a tension-free manner, and how important it was to have that completed before removing the covering of the product, the sheath that was a part of the product. Those were -- those were the areas that we primarily discussed with these procedures.

Q What did you tell them about the trocars?

A I suggested that the trocars were possibly larger than they needed to be. We had not had any specific issues during all of those early cases when

the majority of bladder injuries seemed to occur. We were able to avoid that. And so I never did see a trocar -- excuse me -- when we were using the metal trocars in my patients. And, of course, part

of my advantage was that we are not a teaching facility and residents do not do our cases or medical students. And so, again, it was always on me as to whether or not there was going -- if there was a complication, it was a complication that either I had created or that was a part of the process of placing a trocar blindly into the space of Retzuis, and ultimately removing.

Q Did Ethicon ultimately make any changes to the size of the trocar in the TVT device?

A In the retropubic procedure, the now TVT Exact, which is, again, a retropubic procedure, uses I think polyethylene or some plastic polymer that is probably about half the original diameter of the metal trocars, and that's what they use now to pass the TVT Exact. Again, a smaller trocar that is of some polymer or plastic, something like that anyway.

Q And do you believe the change in making the trocars smaller is an improvement to the TVT device?

A You know, I don't really know if it is an improvement, if they're reporting fewer bladder

injuries. And that's where that change would be reflected, I would believe. I am not aware that there have been any publications in the TVT Exact literature that would suggest that they're seeing fewer bladder perforations with this new trocar as compared to earlier use.

Q Do you currently use the TVT Exact?
A Yes, I do.
Q Do you currently use the TVT retropubic device?
A No, I haven't been. I don't believe our hospital stocks that any longer.
Q Okay. When did you start exclusively using the TVT Exact device?
A I would guess that it's been now probably about two years.
Q Do you still use the TVT obturator device?
A Yes, I do.
Q Have you ever used the TVT Abbrevo?
A I have on two or three occasions.
Q Did you not like the TVT Abbrevo device?
A No. I liked it a great deal. We just were unsuccessful convincing our hospital to stock that.
Q And did you make an effort to convince the hospital in which you practice to purchase the TVT Abbrevo device?

A I did. They have forms that a physician can fill out with their sense of whether or not this product is any better or is going to be less expensive. And I did fill out those forms but was unsuccessful.

I was actually the only physician at our institution that was interested in bringing that product into the -- into the hospital.

Q And why did you make an effort to convince your

hospital to purchase the TVT Abbrevo device?
A I just -- I felt very comfortable using it and it seemed to work well. It was easy to tension. And, again, I just -- I only had two or three opportunities to really use it, and so really can't form a very educated opinion based on either the improvement or lack of difference between the other obturator procedures.
Q Did you make an effort to convince your hospital to purchase the TVT Exact device?
A No. That just simply appeared. And I'm not sure if other physicians at our institution were instrumental in bringing that on board. They must have been, but I was not a part of that.
Q Have you used any other slings besides Ethicon manufactured slings?

A I've used autologous fascia lata. I've used cadaveric fascia, and I did use a Boston Scientific Outside-In sling on one occasion.
Q Other than using a Boston Scientific sling on one occasion, you have exclusively used Ethicon products when implanting polypropylene mesh for the treatment of stress urinary incontinence; correct?
A That would be correct.
Q When did you use fascia slings?
A I would guess that it's been -- it was in the 1990s that I was using fascia lata.

Q When you used those slings, did you consider them to be safe?
A Yes.
Q When you used those slings, did you consider them to be effective?
A At the time I did. Subsequent research has shown them to be poorly durable and frequently fail.
The other issue that we identified with the fascia lata slings was an increased frequency of retention and de novo urgency.
Q And does the TVT Exact use laser cut mesh or mechanical cut mesh?
A They use laser cut mesh.
Q Do the TVT obturator mesh products you

currently use utilize laser cut mesh or mechanical cut mesh?
A I believe we receive both of those products at our hospital. Did I answer that correctly? The TVT-O uses both laser cut and mechanical cut mesh.
Q So fair to say that you currently implant both mechanical cut mesh and laser cut mesh TVT obturator devices?
A Yes.
Q Do you ever track, in your patients, whether you used a laser cut mesh or mechanical cut mesh when you implant a TVT obturator device?
A No. I have to admit I'm, frankly, never aware, consciously, of whether or not the mesh that I've

implanted is a mechanical cut mesh or a laser cut mesh. I simply have seen no difference between the two, and I never ask myself that question when I'm at the point of implanting them.

Q Have you ever designed a medical device, Doctor?

A I think -- can I ask you to be more specific and give me a definition that's maybe a little expanded regarding design? You know, I spoke -- I'll continue for just a minute. I spoke to the fact that, in the course of initiating my

utilization of the retropubic midurethral sling, that we were in very close contact, with each procedure, early on, with the Ethicon rep, and I'm assuming his superiors and the people that were a part of design. And so, to that extent, I believe that I have been a part of and potentially responsible for some of the design changes that may have occurred, so if that answers your question.

Q Yes. Other than providing feedback to Ethicon sales representatives about your early use of the TVT retropubic device, is there anything that you want to add related to your experience in designing a medical device?

A No.

Q And do you hold any patents, Dr. Fiegen?

A No, I do not.

Q Now, going back to the feedback that you provided to Ethicon sales representatives when you first started using the TVT retropubic device, we talked already about the feedback you provided related to making the trocars smaller. We haven't yet talked about the feedback you provided about tensioning the device. Can you tell me more about the feedback you provided to Ethicon about tensioning the TVT retropubic mesh?

A Well, early in the process, the Ethicon reps were very useful in allowing us to spend time with the mesh itself and stretching it, and basically that was what we were doing when we would tension this material. And so I realized very early in that process that, without the sheath in place, that attempts at tensioning the midurethral sling would lead to stretching of the product, and that was what we did not want to happen.

And so my suggestion to them was that for physicians, who are early in their utilization of this product, that they feel comfortable with the tensioning that occurs before the sheath is removed, and to not attempt to change the nature of that tensioning once that has occurred, once the sheath has been removed.

Q Once the sheath is removed from the TVT product, fair to say that you instructed Ethicon to tell physicians not to further tension the mesh?

A I did.
Q And the reason for not tensioning the mesh after the sheath has been removed from the patient is that the mesh would stretch. Is that fair?
A Yes, it does. And then immediately when doing that we have now moved from a tension-free placement

to the placement of mesh under tension.
Q After the TVT mesh is implanted inside the patient's body, are there any forces or stress from the body that are placed upon the mesh?
A Yes. Of course.
Q And can you explain that further?
A When a patient strains, bears down, goes from a sitting to a standing position, all of those events, coughing, laughing, increase abdominal pressure. And that will transfer -- some of that pressure then transfers to the midurethral sling. And that's why the sling works so effectively. It remains positioned properly, and it allows for a mechanical obstruction of the urethra and allowing the patient to remain dry.
Q Now, Doctor, you are a member of the International Continence Society; correct?
A Correct.
Q Are you familiar with the transvaginal mesh complication classification system published by the International Continence Society?

A I haven't seen that recently, I have to admit.
Q Have you reviewed medical journal articles related to transvaginal mesh for the treatment of stress urinary incontinence that have associated the

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use of mesh with urinary retention?
A Yes. Yes, I have.
Q Have you reviewed medical journal articles related to transvaginal mesh for the treatment of SUI that have associated the use of mesh with chronic vaginal pain?
A I've read in some literature, there have been -- there's been that suggestion. Of course, that occurs very, very infrequently and at very low rates.
Q And have you reviewed medical journal articles related to transvaginal mesh for the treatment of SUI that have associated mesh with chronic dyspareunia in women?
A Again, basically the same answer. Many of the literature articles have addressed that issue, but it occurs so very infrequently that some of them simply do not, because, again, the reported incidence of dyspareunia is approximately .2 percent of all of these cases.
Q Have you reviewed medical journal articles that have found that the TVT mesh can migrate inside of a patient after it's placed?
A I've read articles that have questioned whether

or not the TVT will migrate, and the overwhelming

majority of these articles have shown no evidence of migration. And those articles that have been done with ultrasound evaluation, again, can objectify those findings very effectively for us.

Q Have you reviewed medical journal articles that have discussed transvaginal mesh for the treatment of SUI shrinking or contracting inside of a patient's body?

A Yes. I've read some of those articles. Most of them, I think. And, again, the overwhelming majority of the well-done articles show no evidence of shrinkage.

And to continue in answering that question, what has been clearly identified is in the wound-healing process that is so very important with the placement of this mesh, that the infiltration of the sling, which is easily accomplished because of its large pore size, the infiltration of the sling with fibrotic material, macro fascias, collagen vessels, all have, as a part of the normal process of infiltration, and with myofibrils, the fibrotic capsule is the element that begins to contract. And that's a normal part of wound-healing, the contraction of the wound. And that is the only -- the only element that can lead to a change in that

way.
Q And you have reviewed medical articles that have concluded that transvaginal mesh for the treatment of SUI contracts or shrinks inside of a patient's body after it's placed; correct?
A I've reviewed articles that have looked at that issue. None of which have shown that to be the case.
Q Okay. You have reviewed medical journal articles that have concluded that transvaginal mesh for SUI can curl or rope inside of a patient's body after it is placed; correct?
A I have.
Q And you have reviewed medical journal articles that have concluded transvaginal mesh for SUI can fray or deform inside of a patient's body after it's been placed; correct?
A I've read articles on that. Again, I believe the majority of the data that we have and the clinical data that we have shows no reason to believe that that -- if that does occur, and the determination of that has to occur with removal of the mesh.

Now, removal of the mesh in and of itself will create curling, will create separation.

Fraying, I think, is the term that you had used. Just the mechanical separation of that mesh from the body will create those events. And so to be certain that that has occurred preoperatively, I believe, is to -- to not exaggerate, but I think is a stretch.

Q When you removed the three TVT obturator mesh products from patients, did you examine the mesh after you removed it?

A Yes.

Q Did you examine the mesh under a microscope?

A No, I did not.

Q So you just performed a gross examination of the removed mesh; correct?

A Correct.

Q And did you -- I assume that you felt the mesh when you removed it from the patient?

A Yes. Of course.

Q Okay. Can you explain to the jury, based upon your gross examination, as well, in your experience of feeling the mesh after it's removed from the patient, what the mesh feels like?

A Well, the mesh feels like the mesh that we implanted when all of the fibrotic material has been removed, but it looks just terrible because we create so much tension and so much pressure on the

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-- in the removal of the prolene mesh that it is distorted terribly at the time of removal.

Q Doctor, once the TVT obturator mesh is implanted inside of a patient's body, is it possible to ever fully remove the mesh?
A I'm sure that it's possible. It's rather difficult to get around the inferior pubic ramus and remove the mesh that extends from the groin to that point.
Q And once the TVT retropubic mesh is placed inside of a patient's body, is it possible to remove the entirety of the mesh?
A It is possible.
Q And have you ever done that yourself?
A No. I've never had to remove a retropubic sling.
Q We talked about removal surgeries. Have you ever performed any mesh revision surgeries where you have released tension on the tape?
A Yes, we have.
Q And are those in addition to the removal surgeries --
A Correct.
Q -- that we talked about earlier?
A Yes. That is correct.

Q So we've got removal surgeries. We've got revision surgeries where you've released tension on the tape.
Have you performed any other mesh revision surgeries other than the two that we've already

talked about?
A I have removed areas of erosion and exposure of transvaginal mesh.
Q So you've performed mesh revision surgeries where you have released tension on the sling; correct?
A Correct.
Q You have performed mesh revision surgeries where you have revised an exposure or erosion of the mesh; correct?
A Yes. That's correct.
Q And you have performed mesh revision surgeries where you have removed parts of the transvaginal mesh from a patient's body; correct?
A Correct.
Q Any other mesh revision related surgeries I'm leaving out?
A No. I don't think so.
Q Okay. How many times have you performed a mesh removal surgery where you have revised an exposed or

eroded transvaginal mesh?
A I would have to guess. I don't keep an accurate number or total, but my guess is somewhere between 10 and 12 exposures that I've removed.
Q Have those involved Ethicon transvaginal mesh products?
A The products that I had placed that led to

erosion, and, I believe, if I'm correct, there were three or four of those. The others that were sent to me, I have to admit I'm not certain whether or not those were Ethicon, or AMS, or Boston Scientific slings. The exposure typically is quite clearly identified, and the area to be excised, again, is very clear.

Q In the three or four mesh revision surgeries, do you recall whether those were TVT products or not?

A Yes. They all were.

Q Okay. In those three or four TVT removal or revision surgeries involving exposure of the mesh, did you make a determination of what the cause of the exposed mesh was?

A In one patient it was very clear. It was her hypo-estrogenic state that led to the exposure of just very small filaments of mesh that were felt at

the time of intercourse. She was having no pain and no discomfort. She chose not to use vaginal estrogen, and we simply went ahead and removed that small segment of mesh that had -- that had migrated through the atrophic vaginal tissue that now existed.

The other patients that I had done -- I'm trying to think back now on their exact clinical circumstances, and I believe one of them was menopausal and the other two were premenopausal.

These were just typically -- my sense was that they were simply separations of the vaginal mucosa that overlay the mesh product, and that they had simply separated, and the reasons for that were unclear to me.

Q In the first patient you described, had her partner felt the mesh during sexual intercourse?

A He had.

Q Fair to say that one unique risk of using transvaginal mesh for the treatment of SUI is a woman's sexual partner feeling the mesh during sexual intercourse?

A I would say that if the mesh erodes through the vaginal mucosa, that's a likely probability.

Q And is that a risk unique to the use of

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polypropylene mesh for the treatment of SUI?

A Are you asking me is dyspareunia unique to --

Q No. I'm asking you what we just talked about, where a woman's partner can feel mesh during sexual intercourse. Is that a risk unique to using polypropylene mesh to treat stress urinary incontinence?

A I don't know if it's unique or not. That the material is, as you know, a permanent polypropylene mesh, and we all know that erosions, exposures can occur, but I couldn't say whether it was unique to this product.

Q Okay. How many times have you performed a mesh revision surgery related to releasing tension on the mesh?

A Again, I have to -- I have to use my best guess. But for my patients, and patients referred to me over the last 17 years, I believe I probably have released as many as 15 slings for patients who were having elevated post-void residuals or urinary retention.

Q And how many of those 15 were patients in which you had implanted a TVT mesh product?

A I would guess, again, that a third to maybe a half of that group were patients of my own.

Q And of your own patients who you performed a mesh revision surgery in which you released tension on the TVT mesh, why was there excessive tension on those patients' mesh?

A I'm sure the reason was that I -- I placed the sling too tightly.

Q Will you be offering any opinion that Ethicon met industry standards for a medical device company in this litigation?

MR. KOOPMANN: Object to form. Go ahead.

A Isn't that what we're doing right now?

Q (By Mr. Jones) Well, what are the industry standards that you're opining that Ethicon met in this litigation related to -- we'll first start with the design of the TVT and TVT obturator mesh.

A I have to say that I'm not aware of any industry standards that existed before this -- before this product was ever brought to market.
Q Did Ethicon ever test the TVT retropubic device prior to launching the TVT retropubic device?
MR. KOOPMANN: Object to form. Go ahead.
A Yes. I believe Dr. Ulmsten had published their results in about -- I think about '96, and then again in '98. And, to my knowledge, the product had been released in Europe at that time, but was not

released in the United States until -- and you can correct me if I'm wrong -- in 1999 I believe it was released by Johnson & Johnson in the United States.
Q And Dr. Ulmsten is the inventor of the TVT; correct?
A Yes. Among other colleagues of his.
Q And I want to be precise here. Did the company, Ethicon, ever test the TVT prior to it being launched by the company?
A I believe that they allowed Dr. Ulmsten to do the clinical research on this product before -- again, before they purchased the product. And, ultimately, as you know, there have been more than 2,000 investigations and articles that have been published that look specifically at the clinical results of using this product.
Q Doctor, how long did you spend writing your

report?
A Well, I have my hours in front of me. And the majority of those hours, when I first started, I believe the very first date that we started was December 7th of last year. And of the 23 and a half hours that I spent in this effort with Mr. Koopmann and on my own, my guess would be somewhere between 18 to 20 hours were spent on preparing this.

Q And did you prepare your reliance list?
A No. No, I did not. Let's see, I want to make sure that I understand. The list of medical literature that we included?
Q Correct.
A No. I did not provide -- I did not create that.
Q Was it important to you in forming your opinions in this litigation to review internal Ethicon company documents?
A You know, initially I must say I hadn't really considered that. But Mr. Koopmann made it possible for -- or made me -- or I should rephrase that.
Mr. Koopmann made available to me those documents and indicated to me the importance of my familiarization with those. And, again, I then began to read through the company documents that I did have.
Q And fair to say then that your review of internal Ethicon company documents was important in

forming your opinions in this case?
MR. KOOPMANN: Object to form.
A The most important thing, to me, in forming my opinions for today is related to my clinical experience as a surgeon and using this product for

more than 17 years, as an early adopter of the TVT-O in 2004, and my review of the voluminous amount of clinical data and medical literature that is a part of this product.

Now, that doesn't mean that I wasn't interested in reviewing documents from the company. My sense was that when I look at a memorandum or an e-mail, that internal communication that existed for the majority of the information that came from Ethicon, was of interest and was valuable, in some circumstances, but was not of the same level of importance that all of the level one data and the clinical sense that I have had and the clinical experience that I have had in forming my opinion.

Q (By Mr. Jones) Did you review internal Ethicon company documents that discussed fraying of the TVT mesh?
A I did.
Q Did you review internal Ethicon company documents that, quote, refer to the TVT mesh as a bad quality mesh?
A Yes. I believe I read a single report. I

can't remember who the author was of that, but I did read that.

Q Did you review internal -- an internal Ethicon

company document that referred to the TVT mesh as, quote, the weak point of the TVT?

A If I did, it's not coming back to me immediately. I may have, but I do not recall that specifically.

Q Did you review an internal Ethicon company document that discussed a 30 to 50 percent shrinkage rule of thumb for the TVT mesh?

A Yes. I did see that report.

Q Did you review an internal Ethicon company document that discussed that during the TVT surgical procedure the TVT mesh would elongate up to 50 percent?

A I read that. Again, what I truly have to go on is my clinical experience, which does not corroborate that suggestion.

Q Did you review an Ethicon internal company document where other physicians in your field reported to Ethicon that the TVT mechanical cut mesh had similar properties as a Scotch-Brite pad?

MR. KOOPMANN: Object to form.

A Again, if I did see that report, it's not coming back to me right now. I don't recall. You said Scotch pad?

Q (By Mr. Jones) Yes. Scotch-Brite pad.

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A I don't know what that is.
Q Do you know what a brillo pad is?
A Yes, I do.
Q Do you recall reviewing an internal document where physicians in your field reported to Ethicon, after examining the TVT mechanical cut mesh, that the TVT mechanical cut mesh had similar properties to a brillo pad or Scotch-Brite pad?
A Yes, I do recall that now. Yes, I do.
Q Do you recall reviewing an Ethicon internal document that referred to the TVT mesh as old construction hernia mesh?
A Yes, I do. Again, I'm not sure that I understood the implication. I have not used hernia mesh myself, and I'm not certain about the distinction between pore size and weight of hernia mesh relative to, and in comparison to, the surgical mesh that's used for midurethral slings.
Q All right. Let's do some housekeeping issues here, Doctor. I'm going to mark for the record Exhibit 1 which is the Notice to take your deposition here today.
MR. KOOPMANN: The court reporter will do that now, Nate.
MR. JONES: Thank you.

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THE WITNESS: Nate, do you mind if I take a break for a bathroom break here while they're doing this?

MR. JONES: Go ahead. Let's take a bathroom break.

(Deposition Exhibit No. 1 marked for identification.)

(Recess taken from 9:38 a.m. to 9:52 a.m.)

Q (By Mr. Jones) Doctor, are you ready to proceed after a short break?

A Yes. Thank you.

Q Is it commonly known among physicians in your field that patients can experience an allergic reaction to the prolene mesh used in the TVT products?

A I can't say that it is. I haven't spoken specifically with very many other physicians/urogynecologists that talk about this. I think it's such an uncommon occurrence that, again, it doesn't come up as a topic of conversation. I have never seen any published research that looks at this issue. We have talked to allergists and dermatologists about methods that we might use to make that determination. And -- but, again, it's not a topic that is frequently discussed, I have to

say.

Q Are you familiar with what a FMEA or Failure Modes Effect Analysis is?
A I believe I am.
Q Do you know the company that Dr. Ulmsten worked with to originally manufacture the TVT device?
A I know the name starts with "M." I'm trying to remember, but I've read, again, that he had a parent company that he utilized and that he developed as a part of his development efforts and marketing for the TVT.
Q Are you familiar with the amount of money Ethicon has paid Dr. Ulmsten to market the TVT device?
A I am.
Q And how much did Ethicon pay Dr. Ulmsten to market the TVT device?
A Well, I believe that there was an initial payment of $250,000 or 200,000. That was followed by a $400,000 investment by Ethicon, I believe, when he released his initial findings and his first report. And, if I'm not mistaken, I believe there was one additional $400,000 investment by Ethicon at the point of time when they were ready to begin the marketing process.

Q And are those payments that you just described all the payments that you're aware of?
A I believe so. Something like -- well, no. I'm

sorry. I just saw -- I believe that there was a total of close to $25 million ultimately paid to Dr. Ulmsten and whoever else that was a part of his organization.

Q Okay. Doctor, we've marked as Exhibit 1, prior to the break, the Deposition Notice. Have you seen Exhibit 1 before?

A No, I have not.

MR. KOOPMANN: Well, have you seen the document --

Q (By Mr. Jones) Did you bring with you any materials to the deposition today?

A I did.

Q What did you bring with you?

A Well, I brought -- if you can hang on for just a second. I brought, of course, my report and all of the articles that I used in formation of that. The remainder of the articles and literature, one that I received are TVT literature, medical literature of other materials, a TVT binder number 2 and 1, and SUI literature binder 1 and 2. I brought thumb drives that had been provided for me, and I

brought CDs of talks that I've given regarding stress urinary incontinence, and urinary urgency, and those issues primarily.

Q Let's mark for the record the thumb drives or thumb drive as Exhibit 2. Let's mark for the record the CDs that you brought as Exhibit 3.

MR. KOOPMANN: Nate, you can do it however you want, but I just want you to know, since it's, you know, maybe a little confusing since you're not looking at what we're looking at. Dr. Fiegen has one thumb drive that contains everything he's been sent. Then there's other thumb drives that will contain that same material but maybe spread out between multiple thumb drives. So you can mark them all if you want, but I just want you to be aware that that is the way it's been done. So if you want mark one, you can just mark that one. If you want to mark them all, you can do that, too.

MR. JONES: Let's go ahead and just mark them all as Exhibit 2.

(Deposition Exhibit No. 2 marked for identification.)

MR. JONES: And, Barry, is there a password for those thumb drives?

MR. KOOPMANN: Yes. There is a black thumb

drive in the envelope, and the password is written on the outside of the envelope, "Mesh2016!"

MR. JONES: Thank you. And then the CDs that Dr. Fiegen has brought with him today can we mark as Exhibit 3?

(Deposition Exhibit No. 3 marked for identification.)

MR. JONES: And then let's mark as Exhibit 4

Dr. Fiegen's expert report.

(Deposition Exhibit No. 4 marked for identification.)

THE WITNESS: Nate, I also have my hours spent and compensation provided for January and February. It dates back to December 7th, and then all the way through January are altogether on one list, and then all of February on a separate list.

MR. JONES: Let's mark that as Exhibit 5. Thank you, Doctor.

(Deposition Exhibit No. 5 marked for identification.)

THE WITNESS: And, Nate, I have an Attachment A that's a consultant invoice between myself and Ethicon.

MR. JONES: Okay. Let's mark that as Exhibit 6.

(Deposition Exhibit No. 6 marked for identification.)

MR. KOOPMANN: That's just another copy of the Notice --

THE WITNESS: Okay.

MR. KOOPMANN: -- and correspondence.

THE WITNESS: This is -- oh. And, Nate, the last element -- last item is correspondence between Mr. Koopmann and myself.

MR. KOOPMANN: Well --

THE WITNESS: I'm sorry?

MR. KOOPMANN: That's not me.
THE WITNESS: Oh, okay.
MR. KOOPMANN: Nate, he's brought along the correspondence that he's received that's responsive to the Notice from various people to him providing materials.
MR. JONES: Let's mark the correspondence as Exhibit 7.
(Deposition Exhibit No. 7 marked for identification.)
Q (By Mr. Jones) All right. Doctor, I want to go through Exhibit 4, which is the report that you issued in this litigation for the TVT and TVT obturator product. Okay?

A Yes. That's fine.
Q Are there any changes or modifications at this time to your report?
A No, there is not.
Q I want to start on page 1 of your report in the "Background" section. Second paragraph that starts with, "During the early years of my practice, I became very involved in the development of minimally invasive surgery and ultimately began teaching other physicians, with a very good and pioneering group of physicians from all over the U.S., the newest surgical techniques in surgery."
What surgical techniques are you referring

to when you wrote that?
A What we're referring to or what I'm referring to is the use of minimally invasive surgery or laparoscopic surgery to treat issues such as ovarian cysts, acute appendices, pelvic adhesions, removal of organs, uterus, cervix, tubes and ovaries, and ultimately we developed a laparoscopic procedure for the Burch procedure.
Q Tell me more about the laparoscopic Burch procedure.
A The approach that we took was to use an extra peritoneal entry into the space of Retzuis. After

our dissection of the areolar tissue that was around the area of the ureterovesical junction, we then utilized prolene mesh, attached that either by surgical tacks or suture to the area immediately adjacent to the ureterovesical junction and extending down to approximately the midurethra.
The opposing end of that prolene mesh was then sutured to Cooper's ligament, and so we had a banding effect that was broader, and, we felt, stronger than placement of two separate sutures as is a part of the originally described tanagho modification of the Burch procedure.
Q The procedure in which you just described, do you still currently perform that procedure?
A No, I do not.
Q Do you perform the Burch procedure with use of

sutures currently?
A No, I do not.
Q Doctor, are you a fellowship-trained urogynecologist?
A No. Fellowships actually didn't exist at the time that I finished my residency. That's sort of, yeah, where I am at. They just did not exist. There was one fellowship under Dr. Ostergard, and when I left my residency training, Peter San had

secured that spot.
Q Doctor, are you familiar with the Urinary Incontinence Treatment Network?
A Yes. I've heard of them.
Q Now, if we move forward to page 5 of your report, and I'm going to read from the very last sentence on page 5 --
A All right.
Q -- of your report. Where you write, "It is frequently performed in combination with other vaginal surgery for pelvic organ prolapse."
You're referring to the MMK procedure in that sentence; correct?
A No, I'm not. I'm referring to the anterior colporrhaphy.
Q Is the TVT commonly performed in combination with other vaginal surgery for pelvic organ prolapse?

A Yes, it is.
Q If we move forward to page 6 of your report.
A Okay.
Q And I'm going to focus in on the last paragraph where you write, "The pores are 1,379 microns and the mesh weighs 100 grams per meter squared."
Are you referring to the mesh used in the

TVT products?
A Yes, I am.
Q And you cite -- you have a parenthetical behind that sentence where you cite to an article by Pam Moalli.
Are you relying on the article that -- in 2008, by Pam Moalli, titled "Tensile Properties of Five Commonly Used Midurethral Slings Relative to the TVT" for support that the pore size of the TVT mesh is 1,379 microns?
A Yes, we are.
Q And are you relying on that article for the fact that mesh used in the TVT products weighs 100 grams per meter squared?
A Yes. I believe that and other articles.
Q Is the mesh that is used in the TVT products and weighs 100 grams per meter squared classified as a heavy weight mesh in your opinion?
A No, it is not. It remains a lightweight mesh and macroporous.
Q Are you aware of any transvaginal mesh products

for the treatment of SUI which weigh less than 100 grams per meter squared?
A Yes, I am.
Q Okay. And what are those products?

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A The two that come to mind are Ultrapro and Vypro mesh.
Q Okay. Fair to say that it's your opinion that the TVT is the gold standard for treatment of SUI; correct?
A Yes. I think it's been reported that way in numerous literature articles written.
Q Do you have an opinion as to when the TVT became the gold standard for treatment of SUI?
A No. Obviously I could speculate, but I don't remember when the very first article describing this as our new gold standard was released.
Q Now, on page 7 of your report you talk about the Ward/Hilton randomized controlled trial comparing TVT to the Burch procedure; correct?
A I'm actually looking for that. Is that in the last paragraph -- okay. Yes. Okay.
Q All right. And you're aware that Drs. Ward and Hilton published two-year results and five-year results of that study; correct?
A Correct.
Q And at two years they found the objective cure rate for TVT patients to be 66 percent; correct?

24 A Correct.
25 Q And at five years they reported that the

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1 objective cure rate of 66 percent in TVT patients
2 declined; correct?
3 A What I read from my report is that at five-year
4 follow-up they found there was no difference between
5 TVT and colposuspension in terms of cure rates.
6 Q Okay. I'm just going to ask you the question
7 again. I understand what you wrote down there in
8 the report, but I'm asking specifically about the
9 objective cure rates that Drs. Ward and Hilton
10 reported at five years which you cite to in your
11 report on page 8.
12 Drs. Ward and Hilton, in their five-year
13 follow-up, reported that the objective cure rate of
14 66 percent in TVT patients declined; correct?
15 MR. KOOPMANN: Why don't you pull out this
16 article if he's going to ask questions about it.
17 A I'm just familiarizing or reminding myself of
18 the results of this article, if that's okay.
19 Q (By Mr. Jones) Yeah. That's fine.
20 A I'm going to have to go to the table, again, to
21 -- at five years it appears that there were 98
22 patients that remained in the TVT group that they
23 had access to. And at five years there were 46
24 patients in the Burch procedure that they saw, and
25 there was no statistically significant difference

between those two at five years.
Q Okay. Back to the question. Do you remember the question I asked you?
A Yes. You were asking me whether or not the one-year data versus the five-year data showed a reduction in the -- in the cure rates, objective cure rates between TVT and Burch procedure. Is that correct?
Q No. That's not what I asked you. Let me ask you the question again.
A All right.
Q And I'm just asking about the objective cure rate for TVT of 66 percent, which you quote, based on the Ward/Hilton two-year follow-up study in your report; correct?
A Correct.
Q Okay. Here's the question: Drs. Ward and Hilton report at their five-year follow-up the objective cure rate of 66 percent in TVT patients declined; correct?
A I have to admit, Nate, I'm still not finding the specific notation. I'll go to the conclusion here and see if I can pick that up quickly for you.
I'm sorry, Nate, I am not finding within this article a suggestion that the rate of objective

continence decreased at five years.
Q What did Drs. Ward and Hilton report the objective cure rate of TVT in their five-year follow-up as?
A I'm trying to find that in this article. You know, Nate, the only thing that I'm finding is that they're reporting that with colposuspension there was an increased incidence of enterocele formation, and that's all I'm seeing. It says, in one paragraph on the last -- second to the last page, "Of women who attended for follow-up, subjective and objective cure rates are maintained at the same level as previously reported at six months and two years. This is compatible with published evidence from case series of long-term cure rates for colposuspension and seven-year results for TVT."
Q Have you reviewed any internal Ethicon company documents?
A Yes, I have.
Q That discuss correspondence between Dr. Hilton and Ethicon about this particular RCT?
A I don't recall that I have.
Q Okay. And are you aware that Ethicon sponsored this RCT?
A I'm sure I would see that if I had the article

back.
THE WITNESS: Barry, that was this one?

MR. KOOPMANN: 70.
A Yes, I see that that's the case.
Q (By Mr. Jones) Now, if we move on to the next paragraph that starts with, "The device has been studied in many long-term studies, even out to 17 years after surgery," which is on page 8. You cite to a study by Carl Nilsson titled, "17 Years Follow-up of Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence."
A Yes.
Q Correct?
A Correct.
Q And are you aware that Carl Nilsson has acted as a consultant for Ethicon?
A No, I'm not aware of that.
Q Okay. Now, I want to skip down to the heading titled "Plaintiffs' Experts' Contentions" on the bottom of page 16.
A Okay.
Q And, first, it's actually on the next page under the title "Cytotoxicity and Foreign Body Reaction."
A Yes.

Q And you discuss an in vitro test Ethicon conducted which showed evidence of causing cell -- or Ethicon -- showed Ethicon conducted an in vitro test which showed evidence of toxicity; correct?

MR. KOOPMANN: Object to form. Go ahead.

A Yes. Cell lysis and toxicity is the way it was presented from Ethicon.

Q (By Mr. Jones) Okay. And you are aware of in vitro testing which Ethicon ran on the mesh used in the TVT products which showed evidence of causing cell lysis or toxicity in vitro; correct?

A Yes. I'm aware of that publication.

Q And do you recall when that testing was performed?

A I do not.

Q And if we skip to the next section titled "Shrinkage/Contraction." The first sentence says, "The TVT and TVT-O slings do not shrink or contract."

Is that an opinion you hold in this litigation?

A Yes, it is.

Q Do you agree that after the TVT mesh is placed inside of a patient's body that scar tissue can form around the mesh and contract down on the mesh?

A I would agree that scar tissue will form around the midurethral sling. To the degree that it may contract, I don't know that anyone can categorically or objectively show evidence that they are able to measure that event. These are small cellular myofibrils that can cause scar contraction. And when that occurs, it's -- again, it's such minute

contractility that they are able to apply, that I'm not sure that it can be effectively measured.

Q And then if we skip down to the bottom of 18 under the title "Degradation," and underneath that title which continues at the top of page 19, you discussed plaintiffs' contentions that polypropylene degrades inside of the human body. Fair?

A Say that again, please.

Q Sure. On page 19 you discussed plaintiffs' contentions that polypropylene degrades inside of the human body. Fair?

A Yes.

Q Okay. And in the first paragraph on page 19 you talk about an article by Drs. de Tayrac and Vincent Letouzey; correct?

A Correct.

Q Are you aware that Dr. de Tayrac has acted as a consultant for Ethicon?

A No, I'm not aware of that.

Q And are you aware that Dr. de Tayrac has had a journal article retracted based upon his misrepresentations concerning that journal article?

MR. KOOPMANN: Object to form.

A No, I was not aware of that.

MR. KOOPMANN: Are you saying based on this journal article?

MR. JONES: I think you know what journal

article I'm talking about, Barry.

Q (By Mr. Jones) Now, on page 20 under the section, "Roping, Curling, Fraying, and Particle Loss," you write, "If the TVT and TVT-O meshes are implanted according to the IFU and Ethicon's training materials, roping, curling, and fraying is not an issue."

Did I read that correctly?

A Yes, you did.

Q Is fraying of the TVT mesh inherent in the design of the TVT mesh?

A No, I don't believe so. Fraying can occur, but it's not a part of the design of this mesh.

Q And then you continue on, "The peer-reviewed published medical literature regarding the slings does not discuss these issues."

And when you write that sentence, "these issues," you're referring to the TVT and TVT-O mesh is roping, curling, and fraying; correct?

A Yes.

Q Are you aware of any peer-reviewed published medical literature regarding slings that discusses roping, curling, and fraying of the TVT and TVT-O meshes?

A I'm sorry. If it does exist, I'm not familiar with it.

Q And then at the bottom of page 20, underneath the section titled "Weight and Pore Size," second

paragraph, second sentence, you're referring to the mesh used in TVT and TVT-O, and you write, "The pores are so large that one can see through them."

Did I read that correctly?

A Yes. Yes. That's what I'm referring to.

Q And are you communicating in that sentence that when you actually hold up the mesh used in the TVT products that you yourself can see through the holes in the mesh?

A You can see light transmitted through very easily. I can't read a newspaper, I don't think, but I can see light transferred, absolutely.

Q Okay. So when you write that sentence, you're

referring to -- you're not referring to your gross examination of the mesh just holding it in your hands. Fair?

A You said I'm not referring to the gross examination?

Q Correct.

A No. I am referring to the gross examination of the mesh. When I hold it in my hands and hold it up, you can see light through it.

Q Okay. And then if you -- further down, now we're on page 21, second paragraph, "Larger-pore, lighter-weight meshes like Ultrapro have been developed, but did not prove to be feasible in Ethicon's testing."

A Yes.
Q Did I read that correctly?
A Yes.
Q Are you aware that Ethicon applied to the FDA for clearance for the use of Ultrapro in a TVT obturator sling?
MR. KOOPMANN: Object to form. Go ahead.
A I'm -- I'm not aware of that.
Q (By Mr. Jones) Okay. So you haven't seen the application Ethicon filed with the FDA to gain clearance for the use of the larger-pore,

lighter-weight mesh, Ultrapro, in the TVT obturator application?
MR. KOOPMANN: Object to form. Go ahead.
A I have not seen that.
Q (By Mr. Jones) And then further down that paragraph you discuss an article by Okulu titled "Use of Three Types of Synthetic Mesh Material in Sling Surgery, a Prospective Randomized Clinical Trial Evaluating the Effectiveness and Complications," published in 2013.
Are you aware of when the enrollment period was for the study done by Okulu on prolene soft mesh, Ultrapro mesh, and Vypro mesh for the treatment of SUI?
A I believe I -- I believe I am. The enrollment period was between --
Q Would you go ahead and take it out?

A Yeah. The enrollment period was between 2005 and 2007.
Q Fair to say that prolene soft mesh, Ultrapro mesh, and Vypro mesh were available to physicians for the treatment of SUI in 2005?
A I would not -- I wouldn't know that, Nate. I have no idea if it was available or was not available. It appears that it was in Turkey.

Q Is it commonly known among physicians that the TVT obturator mesh would be extremely -- would be extremely difficult to fully remove from a patient's body?
A You know, I have not had those discussions with other physicians. There is no question that due to the anatomical issues associated with that, that removal of 100 percent of the mesh would be more difficult with the transobturator procedure than with the retropubic procedure.
Q And I know I've asked you this -- the commonly-known question a couple of times and you've kind of had the same response, about, hey, look, I'm not -- it would be difficult for me to know because I would have to talk to, you know, a bunch of physicians. I think that's what you're saying.
But is it fair that in order for you to render an opinion of what risks were commonly known among physicians in your field, you would need to do

some research and survey physicians in your field?

MR. KOOPMANN: Object to form.

A For me to know what each physician finds difficult surgically, again, would simply require conversation and discussion.

Q (By Mr. Jones) Now, back up on page 21, the top

of page 21 of your report. You talk about the Amid or Amid classification of Type 1 meshes; correct?

A Yes. Correct.

Q And you're aware that that classification is for mesh used in abdominal wall hernia surgery; correct?

A Yes, I'm -- I'm aware of that.

Q Doctor, do you know who Richard Isenberg is?

A I'm sure I should. I'm trying to recall if he was one of the Ethicon researchers. I can't recall, honestly.

Q Okay. Do you know who Dr. Martin Weisberg is?

A Again, I believe that I read his name in an Ethicon draft or report.

Q Do you know who Dr. Pete Hannula is?

A Pete? What was his last name, did you say?

Q Hannula?

MR. KOOPMANN: Hannula.

A No, I'm afraid I don't.

Q (By Mr. Jones) Do you know who Dan Smith is?

A Well, I know a Dan Smith, but I'm --

Q I was going to say, in relation to this

litigation do you know who Dan Smith is?
A I don't recall.
Q Okay. Do you know who Laura Angelini is?

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A Gee. No, I don't recall.
Q Do you know who Jean Kammerer, K-A-M-M-E-R-E-R, is in relationship to this litigation?
A No, I do not.
Q All right. Doctor, I want to ask you a question about testimony from an Ethicon medical director that was presented at trial for the TVT obturator product. And he was asked, hypothetically, if the company knew the TVT device was associated with chronic pain, chronic debilitating pain, is that something you believe should have been included in the IFU. And he answered, "If the company knew that, yes."

Do you agree with the testimony given by an Ethicon medical director that if Ethicon knew that the TVT devices were associated with chronic pain, that Ethicon should have included that in the TVT IFUs?

MR. KOOPMANN: Object to form.

A To begin with, the product does not cause chronic pain, and so, therefore, I don't know why they would be compelled to report on that.
Q (By Mr. Jones) Okay. Assume under my hypothetical that the TVT devices do cause chronic

pain. And assume that Ethicon knew that the TVT

devices could cause chronic pain. Should Ethicon then have warned of chronic pain in the TVT IFU?

A You know, I'm not quite sure, Nate, exactly why we would play this hypothetical game. It does not cause chronic pain and there's no point to soliciting suggestions about a hypothetical.

Q Yeah, there is a point to it. I know it might seem a little gamey, but it's my opportunity to ask questions about your opinion specifically about what should have been in the IFU. And so, in this hypothetical, you're going to assume that Ethicon knew that the TVT device could cause chronic pain in women. And under that situation, would Ethicon then be required to include chronic pain in the TVT IFUs; yes or no?

MR. KOOPMANN: Object to form.

A If we -- if we assume and make this giant leap to suggest that chronic pain was understood by Ethicon, and did know, there is obviously -- it would be reasonable for them to be accountable for -- to provide that information to physicians if it was not an occurrence that was known by them.

Q (By Mr. Jones) Is it your opinion that Ethicon -- well, let me ask it this way:

Do you believe that Ethicon should not

avoid warning about risks associated with a product just because Ethicon assumes that doctors know about that risk already?

MR. KOOPMANN: Object to form. Go ahead.

A That degree of redundancy makes no sense to me. Every physician, every surgeon has an extended discussion with their patients. They're given materials regarding whatever surgical intervention is being suggested to them, and each patient will sign a very detailed consent form that spells out all of those things.

I don't see the need for specific redundancy on the part of Ethicon. If they report to us in the way that I -- in the way that I suggested, you know, providing us with an understanding, if there is something that is not understood, if we do not know of an issue that is likely to develop, then it's their responsibility to provide that information for us.

But, otherwise, they don't need to tell patients that there's a risk of infection. There's a risk of pain following procedure. There's a risk of failure. There's a risk of voiding dysfunction. Those are all issues that are addressed by the physicians or his or her representative. And,

again, I don't see the need for redundancy in that circumstance.

Q (By Mr. Jones) Does Ethicon need to tell doctors that the TVT obturator mesh is extremely difficult, if not impossible, to fully remove from the patient's body?

MR. KOOPMANN: Object to form. Go ahead.

A No. They don't need to tell physicians that. If the physicians are uncertain about that, they can make that inquiry. But I don't believe that any physician that performs this procedure, the transobturator procedure, would have any uncertainty about the technical difficulties of removing this material.

Q (By Mr. Jones) All right. Now, I'm going to review some testimony from an Ethicon medical director that was presented at trial in a TVT-O case and ask you if you agree with his testimony.

An Ethicon medical director testified that all complications known to the company that relate to the device should be included in the device Instructions For -- the device Instructions For Use. Do you agree?

MR. KOOPMANN: Object to form.

A I believe that, again, any -- any issue that is

product, needs to be identified.

Otherwise, frankly, they don't have to do the physician's work for them. It's the physician's responsibility to make patients clearly aware of all of the potential issues which may arise. And to simply have it on a sheet or an IFU means very little to most patients, and half of them are likely not to read it. And so the discussion needs to occur between physician and patient. And, again, my sense is that that -- that level of redundancy is of no particular use.

Q (By Mr. Jones) Can you name one risk of the TVT devices that is not -- and I'm going to use your words here -- can you name one risk of the TVT devices that is not clearly understood by physicians that Ethicon needs to include in the TVT IFUs?

A I'm not aware of any.

Q Is it your opinion that Ethicon should include in the TVT IFUs the risk of the TVT mesh becoming exposed in a patient?

A Yes. That's relatively unique to this product or other products of its like that we've used, and I

do think that that's appropriate to warn physicians about.

Q Are there any other risks besides exposure of the mesh that Ethicon should include in the TVT Instructions For Use?

A My understanding -- my reading of the IFU suggests that they have covered virtually everything. And that, again, my -- my feeling is that this is an important step in this process for patients, and, that is, their level of understanding that can only be achieved through discussion and questioning with their physician. And, again, I don't believe that there's anything within the IFU right now that is lacking or leaves physicians in a position of vulnerability or patients.

Q And what are the risks, besides exposure of the TVT mesh, that Ethicon should include in the TVT IFUs?

A I believe they have included everything that I would feel is important. And, again, if all they were reporting was that exposure or erosion of this material can occur transvaginally, and that there is a certain percentage of likelihood of that. If they wanted to put that in, that would be adequate, I think.

Again, this is a surgical procedure. Physicians are aware of the issues associated with the surgical procedure, and it's their responsibility to make patients aware of that.

Q When you said earlier that you feel that Ethicon has included all of the risks associated with the TVT devices in the product IFU that you believe they should have, are you referring to the

2015 TVT IFUs?
MR. KOOPMANN: Object to form.
A No. I'm referring to the original IFU.
Q (By Mr. Jones) Do you know why Ethicon changed the Instructions For Use, specifically the warning statements in the 2015 TVT IFUs?
A No, I don't -- I don't know. Obviously, I could speculate, but that would be inappropriate. I do not know what conversations occurred within the company, within the senior advisers or their scientists that caused them to move forward with a publication that, in my opinion, again, is particularly redundant.
Q And you haven't read any deposition testimony that has discussed why Ethicon made the change to the 2015 TVT IFUs?
A No, I have not.

Q Have you ever been asked by any regulatory agency to review the adequacy of Instructions For Use for a medical device?
A No, I have not.
Q And outside of your work related to your report that you have issued in this litigation, has any medical device company ever asked you to review the adequacy of their Instructions For Use for a product?
A No, they have not.

Q And we talked earlier today about the feedback that you provided to Ethicon in your early use of the TVT retropubic device that involved comments that you gave to Ethicon about the trocars and the tensioning of the mesh.

Did Ethicon ever ask you to provide any feedback about the Instructions For Use, specifically what risks were included in the Instructions For Use related to the TVT line of products outside of this report that you've issued?

A No. I was never asked about that or asked for a recommendation, suggestion, anything specific to their IFU.

Q And outside of your work on this case -- well, let me ask it this way:

Outside of your work on this case, Doctor, do you routinely review the Code of Federal Regulations on what is to be required in a medical device Instruction For Use?

A No, I typically do not.

Q Okay. And I'll ask it broader. I think I already know the answer. And I'm not trying to play games here. But in your clinical practice, as a physician, do you routinely refer to FDA device labeling guidance documents?

A I am uncertain about what you're referring to, Nate. But, you know, when we begin using a new medical device, again, we are in direct contact with

the medical -- the representative who's presenting this as a new, improved, or completely different product than we have had access to. Again, and they leave volumes of information with those of us who may potentially use that. And I can't recall very specifically or directly that that material was consciously reviewed or not reviewed. I just -- I don't recall.

Q So you don't have any recollection of a -- and when you're talking about representatives from the company, you're talking about Ethicon's sales representatives, for example; correct?

A Or representatives from any device company.

Q Okay. And you're talking about sales representatives from any medical device company; correct?

A Correct. And, typically, when we're introducing a new product, there's more than just the sales representative. There are company representatives that are also a part of that.

Q And those are company representatives from the marketing department; correct?

A Or from the research and development department.

Q As you sit here today, can you name one representative from Ethicon from their research and development department?

A No, I cannot.
Q Doctor, are you aware of a long-term randomized controlled trial with the primary end point of pain on the TVT products?
A I am.
Q Was the primary end point obtained on the TVT obturator product?
A Yes, I am.
Q Are you aware of a long-term randomized controlled trial with a primary end point of

dyspareunia on the TVT obturator product?
A No. I don't recall that as a primary end point.
Q Are you aware of a long-term randomized controlled trial with the primary end point of dyspareunia on the TVT retropubic device?
A No. I'm not aware of a specific article that used that as a primary end point or primary goal of determination.
Q Have you ever reviewed any studies comparing TVT laser cut mesh with TVT mechanical cut mesh --
A Yes, we have.
Q -- published in peer-reviewed medical literature?
A Yes.
Q And what study would that be?
A I'll have to look back. I cannot find the articles that speak specifically to that. And as I

reconsider, Nate, I may have misspoke. I'm not positive that I have read an article that discusses specifically the differences between laser and mechanically cut mesh. I'd like to amend my first suggestion.

Q Okay. Are you familiar with a product used to treat stress urinary incontinence named Repliform?

A Yes. I can't recall precisely what that is. The name is quite familiar. If I remember correctly, it was a different type of material used in the same fashion as the midurethral slings.

Again, I'm trying to remember exactly whether or not that's the case, and so maybe I'm asking the question this time. I believe that it was a biologic product that was used as a transvaginal sling.

Q I think you know your stuff. All right. I'll continue on.

A What? I don't -- I didn't get that.

Q I said it sounds like you know your stuff. I'll continue on.

A Oh, thanks.

Q It was a compliment.

A I thought he was saying to get stuffed.

Q All right. Doctor, I'll shift gears here now and ask you about some of your past interactions with Ethicon over the years based on our research

into Ethicon's internal documents.

First, I want to ask you about, have you attended AUGS meetings?

A Yes, I have.

Q Have you attended AUGS annual convention?

Pat L. Beck, Court Reporter
605.351.8200 stenopat@sio.midco.net

A Yes.

Q And at those conventions and meetings, do you interact with representatives from medical device companies?

A Yes, we do.

Q Do you interact with representatives from Ethicon at AUGS conventions and meetings?

A Yes, we do.

Q And have you had interactions with Ethicon representatives at what are commonly referred to as medical device booths at these conventions?

A Yes. That's typically the site where that engagement can occur.

Q Okay. Have you ever had dinner with Ethicon representatives that have occurred during the time in which an AUGS convention was held?

A Yes, I believe I have.

Q Okay. And, Doctor, do you recall sometime in 2003 being an Ethicon preceptor for the TVT device?

A If you say that it was 2003, I did precept one physician that I can recall somewhere in that time frame.

Q Doctor, are you familiar with the group AAGL?

24 A Yes, I am.
25 Q And what is AAGL?

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1 A American Association of Gynecologic
2 Laparoscopists.
3 Q And have you attended AAGL meetings and
4 conventions?
5 A Yes. Yes, I have. Particularly early in the
6 years when I was teaching around the country with a
7 number of AAGL members and people that were a part
8 of this group that I had the privilege of working
9 with and teaching with. During those early years of
10 the '90s and up to 2000 I was a very active member
11 of that group.
12 Q Okay. And did you interact with Ethicon
13 representatives at AAGL conventions?
14 A You know, I would guess that I probably did.
15 It's been long enough ago that I don't remember any
16 specific interactions. If you're referring to any
17 dinners or anything, I do believe that there was one
18 evening in Orlando, and I can't even remember if
19 this was Ethicon or if it was some other medical
20 device company, but, yeah, we were taken to dinner
21 one night while I was in Orlando. And, again, I
22 cannot recall if it was the Ethicon company or not.
23 Q Doctor, did you ever do any presentations
24 regarding the ProLift+M product?
25 A No, I never have.

Q Did you ever use the ProLift+M product?
A No, I did not.
Q Did you ever use the ProLift product?
A Yes, I did.
Q It sounds like you have used the Ethicon TVT Abbrevo product on two or three occasions; correct?
A Correct.
Q You have used the TVT retropubic Ethicon product up until two or three years ago; correct?
A Correct.
Q You currently use the TVT Exact Ethicon product; correct?
A Correct.
Q You currently use and have used extensively the TVT obturator Ethicon product; correct?
A Correct.
Q You have used Ethicon's ProLift product; correct?
A Yes.
Q How many times did you use the ProLift mesh product?
A Again, this takes me back a little ways, but I would guess somewhere in the range of 10 to 12, maybe 13 times.
Q Why did you stop using the ProLift mesh?

A Well, I guess it was as much because of certain patient's selection that I would choose to do native tissue repairs, and then as we began to get closer and closer, in 2008, to the FDA's initial warning to physicians, I guess I just simply chose to completely back away from that until the smoke had cleared, until it became obvious through studies which followed, interestingly, that did show a true advantage of an augmented repair in the anterior compartment, but it took a while after that for this information to become clear.

It became clear that biologics had no advantage over native tissue repairs, and it became clear that the posterior compartment was not -- the recurrence rate within the posterior compartment was no different after an augmented repair versus a native tissue repair.

Q When did you start using the ProLift mesh product, Doctor?

A I'm trying -- it was about 2006, maybe near the end of 2006, beginning of 2007, and then into 2008.

Q And after 2008 you never used the ProLift mesh product again; correct?

A No. No. And I'm trying to remember when the company introduced the Prolene M, but it was

introduced as a replacement for the ProLift, the original ProLift, but I just simply never again got on board after that.

Q Did Ethicon approach you or did you approach them about you first starting to use the ProLift mesh product?

A The Ethicon representatives approached me, and they had -- because I was doing the majority of the midurethral slings that were an Ethicon product, they invited me to a course that they put on in Omaha, Nebraska, to introduce me to this. And I went to that course, looked at the procedure. I knew Dr. Kevin Benson, who, at that time was in Watertown and doing this procedure. I engaged him.

I attended the surgeries -- some of the surgeries that he had done, and then subsequently Dr. Benson joined me in Sioux Falls, and as partners we interacted in that way. But, yeah, again, that was -- my introduction came through the Ethicon representatives and an introduction in the Omaha area at one of the hospitals there, and then ultimately continuing that with my partner and current partner.

Q And I know you answered this already but just

to be clear, you never used the ProLift+M mesh product; correct?

A No, I never did.

Q Did you ever use the TVT Secur product?

A I'm guessing probably two or three times.
Q Why did you not use the TVT Secur mesh product more than two or three times?
A I just simply did not like it. And part of the issue was related to the integral theory that Ulmsten and Petros had provided for us, and that made it easy to understand why we were shifting to a midurethral sling that was not fixed in position. I simply did not like the fact that the Secur was fixed in position.

I had no issues with it in any other way, but I just did not want to, again, violate that theory that had been so useful for us and that had created such a successful product.
Q And when you talk about -- when you talk about a fixed system, you're talking about the anchoring mechanism --
A Correct.
Q -- that is used with some transvaginal mesh products that fix the mesh when it's placed by anchoring -- by using different sort of anchoring

mechanisms; correct?
A Yes. That's what I'm referring to. The anchoring effect of the TVT Secur.
Q And based on your review of the Ulmsten series and his technique, the revolutionary aspect of the TVT product was that there was no anchoring

mechanism required; correct?

A That was simply part of the theory. And the remainder of the integral theory talks about the different mechanisms that are -- that are occurring throughout the urethra and particularly at the mid-urethra. And so the movement of the sling's position from the urethrovesical junction to the mid-urethra and a lack of -- a lack of fixation of this material made it possible for this to all develop as it did.

As you know, Dr. Ulmsten was using many other products in this development. And the majority of those products that he was using were fixed in position. And they saw very high erosion rates, in the 14, 15 percent range. And they progressively and ultimately came to use the polypropylene mesh and became aware of the fact that they just did not have to anchor this mesh. And that started this entire process that has, again,

brought us to a point where now we can call the midurethral sling the gold standard of female anti-incontinence procedures.

Q And the reason for an anchoring mechanism, or at least the thought was, the need for an anchoring mechanism was to hold the mesh in place once it was implanted inside the body; correct?

A That's correct.

Q Okay. And because of the high degree of

friction between the mesh and the patient's tissues, the prolene mesh used in the TVT does not need an anchoring mechanism; correct?

A The TVT is very adherent. I don't agree that there's such a great degree of friction, otherwise we'd see significantly more erosions, both into the bladder, urethra, and through the vagina. It's just -- it's much more adherent.

Q And when Ulmsten wrote one of his papers in 1996, he specifically used the words "high degree of friction."

A He did -- I didn't --

Q Do you remember that?

A No, I don't remember that.

Q And when Ethicon dispersed clinical sales aids to physicians regarding the TVT, they claimed there

was a high degree of friction?

MR. KOOPMANN: Object to form.

Q (By Mr. Jones) Do you remember that?

A No, I do not. You know, Nate, I'm just kind of wondering if we're dealing with just semantic differences that can make this sound more problematic or not. You know, when you place a -- this prolene mesh against a subcutaneous area of tissue, it adheres very effectively. And that happens when you simply lay that on that subcutaneous tissue and it just becomes adherent.

Again, there may be a certain degree of movement of the sling after it has been placed and tensioned, but very little. And so I don't quite understand your need to refer to this as friction or clinging to that suggestion. It may have been, semantically, the term used by Ulmsten and a few others, but there's very little friction that is created in this situation.

Q Well, they're not my words. They're the inventor of the TVT's words in a peer-reviewed published medical journal article.

A I understand.

Q Where he said "A high degree of friction." So it's not something I'm making up, Doctor. I'm just

reading from the article.

A No. I understand. I understand. What I'm suggesting is that there is so little movement with this product, after it's been placed, that the idea of this being frictional or creating issues because there's friction here, I think, was something that they probably misspoke about because there's very little movement of this product once it's been in place because it becomes adherent to that subcutaneous tissue.

Q Well, I'm about ready to move on, but just one final question. Do you think that -- and if we want, I can show you the article. It might save time not to.

But do you think that when Dr. Ulmsten described there being a high degree of friction with the polypropylene mesh, used in the TVT device, that he misspoke when he used the term "high degree of friction"?

A You know, I couldn't -- couldn't say, Nate. You know, it's speculative probably on both of our parts, and maybe what Dr. Ulmsten was suggesting was that with significant degrees of movement of that material through tissue that there appeared to be a greater degree of friction, but, believe me, I'm

suggesting to you that it's adherence and it's not friction that's occurring.

Frictional occurrences are the result of the rubbing of two objects together that creates heat and sometimes change in whatever the materials are that are in direct contact with one another. That just does not occur with the midurethral sling.

Q All right. Have you heard the term "Velcro effect" in relationship to the TVT products?

A I've heard the term.

Q And what does the term "Velcro effect" mean to you in relationship with the TVT products?

A It means adherence to the subcutaneous tissue.

Q Let's go ahead and get that Ulmsten article out and I promise then we'll move on from this friction talk, but I just want to get the article marked as

an exhibit. And I think we're at Exhibit 8. And if we could go ahead and mark the 1996 original article titled, "An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence," by U. Ulmsten, and with the Bates number at the bottom right of the first page of Eth.Mesh 04558832.

(Deposition Exhibit No. 8 marked for identification.)

Q (By Mr. Jones) Thank you. Doctor, do you have Exhibit 8 in front of you?
A I do.
Q Okay. If you could turn -- you've seen this article before, haven't you?
A Yes, I have.
Q If you could turn to page 4 of 6 underneath the "Discussion" section.
A Yes.
Q And we're going to focus on the second paragraph underneath the "Discussion" section about three sentences down that starts with "In fact."
A Okay.
Q And Dr. Ulmsten writes in this article, "In fact, it was found that due to a high degree of friction the prolene sling was difficult to move as soon as the surrounding plastic sheath had been removed."

Did I read that correctly?

A Yes.
Q And do you agree with that sentence by Dr. Ulmsten or disagree?
A No. I agree that movement of the sling of any appreciable distance after -- after the sheath has been removed is difficult because the sling adheres

as much as it does, and, again, with movement through the tissue, obviously there will be a resistance or a frictional effect.
Q Okay. Doctor, do you recall giving any discussions in 2011 to Ethicon representatives at Sanford Medical Center in Sioux Falls in January of 2011 specifically?
A Do I remember -- what kind of interaction are you referring to?
Q Dr. Michael Fiegen to discuss his extensive use of TVT-O and limited use of TVT Abbrevo at Sanford Medical Center January 11, 2011, with Ethicon representatives.
A If that occurred, I believe you. I can't remember it, though.
Q Okay. All right. I want to mark as Exhibit 9 an article titled "Evaluation and Management of Midurethral Sling Complications" from April 18th, 2016.
(Deposition Exhibit No. 9 marked for identification.)

Q (By Mr. Jones) Doctor, have you seen this article before?
A Yes, I have.
Q Do you know who the authors -- are you familiar

with any of these authors?
A I know Roger Dmochowski and I know Melissa Kauffman who is in his department.
Q They're both at Vanderbilt University; correct?
A Correct.
Q And how do you know Roger?
A I've known him for quite some time. He's an active member of AUGS and ICS, and I see him at conferences primarily.
Q Okay.
A And Melissa has been to our -- to our office in Sioux Falls. We're a part of a Cook -- stem cell study, and Melissa is very involved at one of the higher levels in that study that's being sponsored by Cook.
Q I want to ask you more about that later once we get through this article. On page 2 of 9, the first full paragraph that starts with "Nonetheless."
Are you with me?
A Yes, I am.
Q Okay. "Nonetheless, certain complications from midurethral sling surgery are unique to the use of polypropylene mesh. These can include mesh exposure, chronic pelvic pain, and dyspareunia,

which are the most common, as well as mesh

contracture, organ perforations, or neuromuscular injuries."

Do you agree or disagree with that statement?

A Well, I agree that any -- any sling, whether it's autologous fascia, fascia lata, cadaveric fascia, any of these procedures can lead to any of these occurrences. I don't think this is -- I would disagree that this is unique to polypropylene mesh.

Q Okay. That's what I was getting at.

A Okay.

Q So you disagree with that statement; correct?

A I do.

Q Okay. Doctor, do you know who Chris Jones, an Ethicon employee, do you remember Chris Jones?

A No, I'm afraid I don't.

Q I want to mark as Exhibit 10 the United States patent by Jean de Leval dated November 3rd, 2009.

A All righty.

(Deposition Exhibit No. 10 marked for identification.)

Q (By Mr. Jones) All right. Doctor, do you know who Jean de Leval is?

A Yes. I believe he's the developer of the Outside-In or Inside-Out. I can't remember which

one it was. I think the Inside-Out transobturator sling.
Q And that's the TVT obturator sling; correct?
A Yes.
Q Okay. And you've reviewed medical articles by Dr. de Leval; correct?
A Yes.
Q And you've reviewed internal company documents where Dr. de Leval has had discussions with Ethicon about the TVT obturator device; correct?
A I believe I have.
Q Okay. And you see that this is a United States patent with a date of November 3rd, 2009; correct?
A Correct.
Q And it says, "Surgical procedure for the treatment of female urinary incontinence, tension-free inside-out transobturator urethral suspension." Correct?
A Yes.
Q And it lists the inventor as Jean de Leval; correct?
A Correct.
Q Does this appear to be a patent related to the TVT obturator product?
MR. KOOPMANN: Object to form. Foundation. Go

ahead.
A I've not seen a patent document prior to this, and so I'm not sure that I'm in a position to be able to answer that question.
Q (By Mr. Jones) Okay. Let's just cut to the chase. Skip to page 17 of 23, and it doesn't look like there's page numbers on it so I can't help you out other than to say it's page 17 of 23 of the document.
And at the top it says, "Surgical procedure for the treatment of female urinary incontinence tension-free inside-out transobturator urethral suspension."
A I see that.
Q Okay. And then there's a section titled "Field of the Invention." Correct?
A Yes.
Q And then below that there's a section titled "Background of the Invention." Correct?
A Yes.
Q Okay. In reading underneath the "Background of the Invention" section, about three sentences down, starting with, "The use of retropubic TVT."
Are you with me?
A Yes.

♀

Q "The use of retropubic TVT has been associated with various and relatively frequent per- and

post-operative complications, including bladder perforation, temporary or persistent retention, pain, urinary infection, and de novo urgency. Other rare but severe and possibly underestimated complications have been reported with this approach."

Did I read that correctly?

A Yes.

Q Do you agree with that statement that I just read?

A What I agree with within that statement is that complications can arise with the TVT, but they're very infrequent and uncommon, unlike their suggestion.

Q Well, let me ask you if you agree with this statement in this patent for the "Surgical procedure for the treatment of female urinary incontinence tension-free inside-out transobturator urethral suspension."

"The use of retropubic TVT has been associated with various and relatively frequent per- and post-operative complications."

Do you agree with that statement?

A No. No. We do not. You know, again, there are very few issues associated with the midurethral sling, whether transobturator or retropubic, and so I would disagree.

This is an effort to get this patent. And

so, to do that, you have to establish uniqueness and -- I forget what all the other elements that are associated with requirements to achieve patent success, but uniqueness is certainly one of them. And utility, I think, is one of the others. And what they're trying to suggest here is that the transobturator sling should replace the terrible and harmful retropubic sling, and this is -- this is just a word game, in my opinion, because that is an incorrect statement.

Q Do you agree that some complications associated with the TVT are underestimated in the medical literature?

A Well, I can't speak to that. I wouldn't know if they were underestimated. I know that is contended by many of your experts that it's terribly under-related, but, you know, the FDA and Ethicon have done just about everything they can to try to maintain effective accountability of complications; the AUGS Society, SUFU, ICS, IUGA, all of those

societies have tried to participate effectively in the proper and frequent accountability and accounting of specific issues.

Some of them go even as far as to report patients who have had urinary tract infections as a complication of this issue. But, again, these societies have done everything they can, as well as

Ethicon and our FDA, to try to make as clear as we possibly can, to all of us physicians who are using this product, what the true risks are for our patients.

We have countless -- more than 2,000 good, published studies that are helping us understand. And, again, you can -- you can throw, you know, stones at these articles and say they just don't pick up all the patients that may have had issues. And, possibly, that's true. But, overwhelmingly, they're so consistent with one another that I can't believe that that is a significant part of what we're missing now.

So, again, that's a long way to answer a simple question, but I think it's necessary to -- to make it clear that there is significant accountability in this area.

Q Doctor, you talked about the FDA reviewing

reports of complications associated with transvaginal mesh. Have you reported to the FDA any complications potentially related to transvaginal mesh?

A No. Typically our complications are reported through the Ethicon system, and I assume that there's sharing of information.

Q The TVT-O removal surgery that you talked about earlier today, did you report those to Ethicon?

A Yes. The representatives became aware of that.

All of our sling revisions for patients who have urinary retention, all of our exposures that are done, all of those patients are reported to the Ethicon representatives and to the Ethicon office.
Q And you report those directly to your Ethicon sales representatives; correct?
A I'm not sure. I don't know that this is a representative -- or a sales rep. I believe that this number that we have to report to Ethicon any of their products that have shown a complication like this, I don't believe it is the sales representative. I believe it's a company representative that takes those calls.
Q And so there should be documentation in Ethicon's records of where you reported each and

every one of these mesh revision surgeries associated with their product; correct?
MR. KOOPMANN: Object to form and foundation. Go ahead.
A I would expect that there are. I'm not sure, with obvious HIPAA requirements or confidentiality requirements, if any of those patients' names are a part of that or the physicians' names. I don't know how they manage that data.
Q (By Mr. Jones) And then you make the assumption that Ethicon then reports that information on to the FDA; correct?

A That is my expectation. That's what I would expect to occur. And these are the same things, I would think, Nate, that AMS, Boston Scientific, Coloplast, any of these companies should be doing.

Q And would it surprise you if Ethicon, after receiving the information from you, did not report that information to any regulatory bodies?

MR. KOOPMANN: Object to form and foundation. Go ahead.

A It certainly would surprise me.

Q (By Mr. Jones) Okay. Did you review any internal Ethicon company documents that discussed TVT obturator being rushed to market?

A Yes, I saw those.

Q And how long did it take Ethicon to get TVT-O to market in the United States?

A I don't know that answer exactly. I know that I began using TVT-O in 2004. That's all -- that's all I know and the only way I can answer that question.

Q Do you think there's anything wrong with a medical device company exclusively relying on a study by the inventor of the medical device prior to the company selling that particular device to patients?

A You know, you're asking two questions. One about study development and how the study was put together, and the other is an ethical question. And

I have no reason to believe that Dr. Ulmsten was not an entirely ethical man. Obviously, he had opportunity to financially be rewarded in this circumstance, but I do not believe that the studies that he did were so poorly biased or contrived that we would have taken a different approach or felt so compelled to have other investigators do that work.

Q And my question's a little different. And I'm just asking whether you think -- whether it's your opinion that it is wrong for a medical device

company to exclusively rely on a study by the inventor of the medical device that the company launches?

MR. KOOPMANN: Object to form.

Q (By Mr. Jones) I'm not asking about the methodology that Ulmsten used. I'm asking a more abstract question of whether it's your opinion that it's incorrect for a medical device company to exclusively rely on a study by the inventor of a medical device prior to the company launching that device?

MR. KOOPMANN: Same objection.

A You know, I think there are issues that need to be addressed. There are concerns that would be unique in that circumstance. But at the end of the day it all comes down to whether the company's representatives, whoever is involved in purchasing

this, has to be convinced that whatever studies that were done, whatever they needed to feel as though this was a product that they wanted to -- to bring into their ownership, is entirely up to them. They have to make that decision. Again, acknowledging the fact that there are pitfalls associated with that, and researcher bias has to be considered.

Q (By Mr. Jones) All right. I have a series of

questions that should go pretty quickly here. Are you an expert in biomaterial science, Doctor?

A Well, again, I certainly helped -- I think I helped in the development and the use of the TVT. I have not ever been involved in biomechanical research at the bench level, only to be a part of the ongoing clinical assessment of this product.

Q Outside of the feedback that you gave to Ethicon during your early clinical use of the TVT product, have you done any work whatsoever with providing consultation on medical devices to companies?

A I don't believe so. I'm just trying to think if -- I don't believe so.

Q Have you ever done any type of pathological analysis or pathology analysis on polypropylene mesh?

A No, I have not.

Q Have you ever published any material on the Burch procedure?

A No, I have not.
Q Have you ever published or written anything on pubovaginal sling?
A No, I have not.
Q You're not an expert in polymer chemistry;

correct?
A I do have an American Chemical Society accredited degree in chemistry. I worked with a number of polymer surgeons doing research during my undergraduate years, but, unfortunately, I can't say that I'm an expert in polymer chemistry.
Q All right. Are you aware that when a patient is implanted with transvaginal mesh, thereafter experiences complications potentially associated with the transvaginal mesh, that more often than not they see a physician who did not implant the transvaginal mesh product?
A No, I would not agree with that. I believe the majority of the patients who have experienced complications from their surgical intervention surface early in their recovery and typically will return to the physician who took care of them, at least that's how it is --
Q What do you base that -- what do you base that statement on?
A On my experience.
Q Is that it?

A Well, is that not enough?
Q All right. Doctor, earlier you brought up -- excuse me -- earlier you brought up some stem cell

research that you were performing with one of the authors of an article that we discussed earlier sponsored by a company named Cook Medical.

Have you used Cook Medical devices for the treatment of SUI in your practice before?

A No, I have not.
Q Are you aware that Cook Medical did manufacture surgical treatments for SUI?
A I suppose I should know that, but I don't recall that I have.
Q Okay. Tell me about the research related to the stem cell work with Cook Medical.
A It involves the harvesting of muscle cells that are taken from the lateral thigh of women. The material is then exported to the Cook laboratories, and it then is processed and goes through about a 6- to 8-week process of identifying myofib -- I can't get that out -- myofibrils and stem cells. The stem cells are already differentiated, I guess is what I should be saying. And when they're sent back to us, those stem cells are then reimplanted into the midurethra of these women. And the initial follow-up, which will be extended, but the initial follow-up and report identifies patients who have had this occurrence, and after one year we reassess

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these patients with not just standard exams, standard gynecological exams, but also with urologic evaluation and assessment of involuntary loss.

These are patients who are experiencing primarily stress incontinence and women who do not have urethral hypermobility. And Melissa Kauffman, you had pointed her out. Melissa is very involved with this same study from Vanderbilt.

Q Doctor, do you know who Aaron Kirkemo is?

A Aaron Kirkemo. No, I don't -- I'm not registering with that.

Q Doctor, do you believe that the presence of the foreign body or the mesh that is used in the TVT-O can be responsible for chronic pain syndromes in patients?

A No. I believe that the inflammatory response with any surgical intervention, any foreign body placement can lead to persistent pain simply because of their ongoing inflammatory process. Again, this is an issue that is so infrequent with midurethral slings as to lead to the question of whether -- why we would, yeah, concern ourselves with that.

I understand why patients are concerned about pain following any surgical procedure, and it should be investigated. And occasionally, because

of the chronicity of those events, occasionally the sling or the other device, whatever it is, has to be sacrificed.

Q Doctor, do you know who Dr. Ming Chen is?

A Yes, I do.

Q Do you know who Dan Lamont is in relationship to this litigation?

A No, I do not.

Q Doctor, do you know Dr. David Robinson?

A David Robinson.

Q Or do you know who Dr. David Robinson is in relationship to this litigation?

A No, I do not.

Q Doctor, do you know who Dr. James Hart is in relationship to this litigation?

A James Hart? Is he the former chairman of Harvard OB/GYN Department?

Q I don't know.

A I think --

Q I honestly don't know. I'm not trying to quiz you. I have no idea.

A You know, I think that --

Q Go ahead.

A -- there was a Dr. Hart, I can't remember if it was James, that was the former chairman of the

OB/GYN Department at Harvard.

Q Doctor, do you know who Dr. Thomas Barbour is in relationship to this litigation?
A Yes, I do.
MR. KOOPMANN: Hey, Nate, when we get to a good stopping point --
MR. JONES: You want to take a break?
MR. KOOPMANN: Yeah. That's what I was just going to ask.
(Recess taken from 12:01 p.m. to 12:19 p.m.)
Q (By Mr. Jones) Doctor, are you ready to proceed after a short break?
A Yes, yes.
Q Okay. We talked earlier about some medical societies such as AUGS and SUFU. Have you reviewed any deposition testimony that has discussed the total amount that Ethicon has paid to medical societies like AUGS and SUFU?
A No, I have not.
Q Are you aware of whether or not Ethicon, when it manufactures the polypropylene mesh used in the TVT products, whether Ethicon uses any antioxidants?
A Yes, I am.
Q Okay. And are you aware of what antioxidants Ethicon uses on its TVT mesh?

A Yes, I am.
Q And what antioxidants does Ethicon use?
A Well, one of them is -- let's see if I can get

these letters correct. I believe it's DLDTV -- DTP and the other is escaping me. It starts with an "S," but I'm aware that there are two antioxidants that are primarily used to coat the TVT slings.

Q When we talked about certain patients who have had an allergic reaction to the polypropylene mesh used by Ethicon, is it possible that the patient's allergic reaction was to the additives?

A I don't think -- I don't think I'm in a position to be able to make that determination.

Q Okay. And then the last series of questions -- I always hate asking these questions, but I wouldn't be doing my job if I didn't ask them.

Have you ever been sued before, Doctor?

A Yes, I have. I had a case early in my career in 1988 of a patient that we did -- how much detail do you want, Nate?

Q Give me all the detail you want to give.

A All right. In about 1988 or '89 I happened to be the only gynecologist that was offering endometrial ablations in this region. And we had about a 43- or 44-year-old lady that presented to us

who was having very heavy menstrual flow and she was requiring blood transfusions to keep her from becoming critically anemic. She had two previously replaced heart valves and so she was on continuous anticoagulant therapy.

It was so important for her that her

cardiologist would not allow her to be -- to allow her to discontinue that product. She was -- she presented to me. We discussed the issue at hand, the approach that included general anesthesia, and a laser ablation of the endometrial tissue, which basically was a cauterizing effect and a destructive procedure attempting to destroy the endometrium within the cavity of the uterus. During that procedure the nurses placed a cautery pad, a grounding pad, from the monopolar cautery unit on her abdomen.

And, unfortunately, there was a wrinkle in that pad, and so every time I used the cautery there was an arcing of that electrical charge across and onto her abdomen. She developed a second degree, about quarter-size blister in that area.

We -- because of this patient's cardiac history, we kept her in the hospital overnight. She did very well. We became aware of the burn and

♀

offered this patient consultation with plastic surgery to look at this, to offer recommendations. She chose not to do that.

The burn was then treated the way we typically would treat any burn. The patient was seen two weeks following her procedure. She was doing very well. I asked to see the burn area. She said it was just fine, and she didn't feel like

taking her shirt off, or whatever, and so we went along.

I saw her again at six weeks. She was -- again, she was doing very well. She was not bleeding at all. And then some two years after her surgery I received a Summons and Complaint that we were being sued because of this injury that she had sustained. Ultimately, this was settled by the insurance company that represented me and by the hospital that I worked at. The malpractice settlement was --

MR. KOOPMANN: I don't know, Dr. Fiegen, if it was a confidential settlement. Do you know that? I mean, I don't want you to get into trouble to disclosing the settlement if it was confidential.

A I don't know. If it was confidential, I probably shouldn't have been told myself what the

numbers were, but it was very low. And that was -- that's the only malpractice case that I've been involved with. There was no trial or there was no -- I never had any direct interaction with the attorney that was representing my patient.

Q (By Mr. Jones) Any complaints to the State Medical Licensing Board, Doctor, that you're aware of?

A No. I'm not aware of any.

Q Are you aware of any medical literature that discusses the particles from the TVT polypropylene

mesh causing pain in patients?
A Yes. I'm aware of those articles.
Q And are you aware of physicians reporting to Ethicon that particles from polypropylene mesh can cause pain in patients?
A No. I'm not aware of that.
Q Okay. As you sit here today, you don't recall seeing a document in which Dr. Hilton reported to Ethicon that particles from polypropylene mesh can cause pain, specifically vaginal pain in women?
A I can't recall reading that specifically. I've heard that suggestion that it would cause -- that it can cause vaginal pain. I just don't remember the specific article that may have suggested that.

Q Okay. Earlier, when we went over your report, we discussed a 2008 article by Pam Moalli that's cited in your report. Do you recall that?
A Yes. Yes, I do.
Q And if you want to get out that article. I'm just going to read you a couple of passages from the article so it might help you to follow along. It might save us both some time here.
A Okay. I'm getting to it right now. Okay.
Q Okay. And right now, Doctor, you're looking at an article by Pam Moalli titled "Tensile Properties of Five Commonly Used Midurethral Slings Relative to the TVT" published in the International

Urogynecology Journal in 2007; correct?
A Okay. Yes.
Q Okay. And this is an article that you cite to in the body of your expert report on TVT and TVT-O; correct?
A Correct.
MR. KOOPMANN: Nate, just for the record, I think you said 2007. It says 2008 on the article.
Q (By Mr. Jones) Sorry.
A Yeah. It was accepted in 2007 and published January of 2008.
Q Yes. Sorry, Doctor. You're looking at an

article by Pam Moalli titled "Tensile Properties of Five Commonly Used Midurethral Slings Relative to the TVT" published in 2008; correct?
A Yes.
Q And this is the same article that you cite to in the body of your expert report on TVT and TVT-O; correct?
A Correct.
Q And, if you can, turn to page 2 of the article.
A Okay.
Q On the left-hand side of page 2 at the top of the page where it starts, "The mesh easily deforms when tensioning under the urethra."
Are you with me?
A I think I must be getting close. Okay. That was midway through the sentence, obviously. The

mesh easily deforms...
Q It says, "The mesh easily deforms when tensioning under the urethra."
Did I read that correctly?
A Yes.
Q And the full sentence, which starts on the page before.
A Yeah.
Q I'll go ahead and read that in full. "For

example, one of the primary problems in using the TVT is that as a result of its low stiffness, the mesh easily deforms when tensioning under the urethra."
I read that correctly; right?
A Yes.
Q Okay. Do you agree with that sentence?
A No, I do not.
Q Okay. And then if you turn to the second to the last page, page 8 of 9 under the "Discussion" section.
A All righty.
Q And focus on the right-hand column of the article, second to the last sentence of the first paragraph on the right-hand column of page 8 of 9.
It starts, "Gynecare mesh permanently elongated by more than 10 percent of its initial length, confirming the easy permanent deformability

of this mesh that is observed clinically during placement."

Did I read that correctly?

A Yes.

Q Do you have any reason to disagree with Dr. Moalli's statement that "Gynecare mesh permanently elongated by more than 10 percent of its initial

length, confirming the easy permanent deformability of this mesh that is observed clinically during placement"?

A Well, I have not done this study myself. Clinically, if this occurs, it leads to no significant issues with regard to success or issues that follow and that can occur with the midurethral sling.

I have no way of refuting her findings because I haven't done the same study. And I can only tell you that when the sling is placed, and it's positioned properly, and it's held effectively in position, that if removal of the sheath leads to a lengthening of the mesh, it has had virtually no clinical significance in my practice.

Q Are you familiar with a product called the I-STOP mesh?

A Would you say that once more?

Q Yeah. It's a product called I-STOP mesh. And it's spelled capital I, dash, capital S-T-O-P.

A No, I don't believe I am.

MR. JONES: Okay. Doctor, those are all the questions I have for you. Barry might have some questions for you, and I might have some questions in response to his, but those are all the questions

I have for now. Thank you very much for your time.

THE WITNESS: Thank you, Nate.

EXAMINATION BY MR. KOOPMANN:

Q Dr. Fiegen, I do have some follow-up questions for you. Does your TVT and TVT-O report that was marked earlier today as Exhibit 4 contain your opinions regarding the safety and efficacy of the TVT and TVT-O devices and their labeling?

A Yes, it does.

Q And do you hold those opinions to a reasonable degree of medical certainty?

A I do.

Q All right. And what are the bases for the opinions that you've provided here today? I mean, is one of the things the medical literature that you've reviewed?

A Of course, yes. The medical literature that I've been reading for many years, more than 20 years, and my clinical experience. All of those -- or those two, in particular, really allowed me to offer my opinions in the way that I have.

Q Okay. And do you practice evidence-based medicine?

24 A Yes, we do.
25 Q What does that mean?

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1 A It means that utilizing the peer-review
2 journals, the systematic reviews, the Cochrane
3 reviews, you allow that to establish, along with
4 your typical societies, standard of care for
5 patients. And that is the approach that you take
6 with all medical procedures or medical therapy.
7 Q And what are considered the highest levels of
8 evidence in the practice of evidence-based medicine?
9 A Well, level one evidence, of course, is
10 important, but the highest levels are the systematic
11 reviews, the meta analyses, and the Cochrane
12 reviews.
13 Q What's the lowest level of evidence?
14 A Discussion with physicians at conference. I'm
15 sorry. Probably -- I believe there's a level four
16 that -- I think there's a level four.
17 Q And where do internal company e-mails and
18 documents fall on that scale of levels of evidence?
19 A It would be at the lowest level.
20 Q Are the complications that you've seen in your
21 practice using the TVT and TVT-O devices consistent
22 with the warnings that are listed in the adverse
23 reaction section of the IFU as it existed before
24 2015 for those devices?
25 A It is.

Q Is it basic medical and surgical knowledge that post-surgical pain can be chronic or temporary?
A It is.
Q Is it basic surgical knowledge that if pain with intercourse presents itself after any stress urinary incontinence surgery that that pain could be temporary or permanent?
A Yes.
Q Is it basic surgical knowledge that when an adverse reaction occurs, further surgery may be required to correct it?
A Yes.
Q Even multiple surgeries?
A Yes.
Q Is it obvious to a pelvic floor surgeon that a macroporous surgical mesh, like the TVT mesh, or the mesh used in the TVT-O, which is designed to have tissue incorporate into the pores, that that could require significant dissection to remove it after the tissue incorporation has occurred?
A Yes.
Q How many TVT retropubic Gynecare slings have you implanted in your career?
A I don't have an exact accounting, but the retropubic procedures -- or of the slings that I've

placed, some 2,400, it would be my guess that 7- to 800 of those have been retropubic slings.

Q And specifically the Gynecare TVT retropubic slings?

A Yes.

Q And how many Gynecare TVT obturator slings have you implanted among those 2,400?

A It would be the remainder. Let's see. 1,800 maybe -- or, no. Yeah, I think that's the right number. 1,700 transobturator slings.

Q So approximately 1,700 transobturator slings and approximately 700 --

A -- retropubic slings.

Q Okay. And out of those 2,400 midurethral slings that you've implanted that were made of polypropylene mesh, how many patients do you think may have experienced an allergic reaction to the mesh?

A Well, I believe that two of them -- two of them did. And that was why we removed their mesh, and they did see almost complete resolution of their discomfort. Again, I have no certainty that this was a true allergic reaction. These patients did not respond to antihistamines. They did not respond to other medical therapy or to injection. And,

again, it -- that was my sense was that this was a rejection due to an allergic-type response.

Q Would it be fair to characterize that sense you had as a hypothesis regarding what was going on with the patients?
A Yes. Absolutely.
MR. JONES: Objection.
Q (By Mr. Koopmann) Would you characterize that sense that you had as a scientific conclusion based on peer-reviewed published evidence?
A No.
Q How many patients would you estimate that you've treated in general who have had a TVT or a TVT-O sling implanted whether by you or anybody else?
A The patients that I have seen from other physicians are typically patients who are either experiencing reoccurring incontinence or they have other related issues that they believe to be associated or to be a part of prior slings that they've placed.
And so, again, I have no absolute count about that, but I'm guessing that since starting our urogyne unit in 2004, I've had 50 to 60 consultations in that regard.

Q Do you have any concerns about placing the trocars of the midurethral slings blindly in the space of Retzuis?
A Well, no. I believe all of us understand the

anatomy in that region, and we understand that if you don't follow the anatomy effectively or appropriately, things like bladder perforation can occur, or vascular injury, or even in some cases there have been a few patients who have had bowel-related injuries. Far fewer now because very few of these patients are done under local anesthesia any longer.

Q I think you mentioned earlier that you currently use the TVT Exact when performing a retropubic midurethral sling procedure; is that correct?

A Correct.

Q And that's what your hospital currently stocks, the TVT Exact?

A Yes.

Q If they started stocking the original TVT retropubic midurethral sling tomorrow, would you use that sling?

A Sure. Yes, I would. I never -- again, I never did ask for the Exact, but it's a very effective and

useful sling. I've gotten so that I really enjoy using that or like to use that, and I think I would be a little disappointed if we had to go back, but that's the way I started, and that sling works very, very effectively.

Q Why did you transition away from using fascia lata slings?

A Because we had way too many failures and we had more frequent urinary retention and de novo urgency with those patients.
Q Have you ever implanted biologic slings for the treatment of stress urinary incontinence?
A Yes, I have. One of those was a porcine dermis product that was recommended to us. Unfortunately, 100 percent of those slings became infected and all of them had to be removed secondarily.
Q Okay. One of the articles that you've reviewed in the course of your work in this case is a Cochrane Review by Ford, Rogerson, Cody and Ogah; is that correct?
A Correct.
Q And this is one of those types of evidence that you said is among the top levels of evidence?
A Yes.
Q Okay. And this was a study that was looking at

randomized or quasi-randomized controlled trials among women with stress urinary incontinence, urodynamic stress incontinence, or mixed urinary incontinence; is that right?
A Yes.
Q And it looked at -- they included in their analysis how many trials?
A Eighty-one trials, I believe it was.
Q And that involved an evaluation of how many

women?
A More than 12,000 women.
Q Okay. And the authors set forth their conclusions in that article; is that correct?
A Yes.
Q And did they say, "Midurethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long-term. This review illustrates their positive impact on improving the quality of life of women with stress urinary incontinence."
Did I read that correctly?

A Yes. Yes.
Q And is this one of the articles that you've reviewed and replied on in forming your opinions regarding the safety and efficacy of the TVT and TVT-O devices?
A Yes, it is.
Q And you were asked some questions earlier about the Amid classification. Do you remember those questions?
A Yes. Yes.
Q And I think the question was, or the discussion was whether that is a classification system used in

hernia repairs. Do you remember that?
A Yes. Yes.
Q This Ford Cochrane Review regarding midurethral sling surgeries references the Amid classification, doesn't it?
A Yes, it does.
Q And it says Type 1 mesh -- well, it talks about Type 1 mesh. Is that a type or one of the classifications in the Amid classification system?
A It is.
Q And it says, "Type 1 mesh has the highest bio-compatibility with the least propensity for infection. Differences in their efficacy and

complications are likely to be due to several factors, including the different knits and weaves of the various type materials -- tape materials, their biomechanical properties and histological bio-compatibility."
Did I read that correctly?
A Yes.
Q And then it says, "Pore size affects the inflammatory response and resultant connective tissue formation within and into the mesh, and the rearrangement of materials, such as collagen, within the mesh structure."
Did I read that correctly?
A Yes.

Q And it says, "Macroporous meshes' pore size in excess of 75 microns easily allow macro fascias, leukocytes, fibroblasts, blood vessels, and collagen to transverse the pores, thus macroporous meshes promote tissue host in-growth with resultant bio-compatibility and low risk of infection."

And it cites Amid; is that correct?

A Yes.

Q And is the TVT mesh that's used in the TVT device and the TVT-O device the Type 1 mesh?

A It is.

Q And this Ford Cochrane Review speaks to the issue of dyspareunia in connection with retropubic and transobturator sling procedures; correct?

A Correct.

Q And it reports that in all the trials they analyzed, there was significant improvement in sexual function from baseline scores during the follow-up period that spanned 6 to 24 months. Is that right?

A Correct.

Q And they noted that there were no significant differences between the two groups?

A Right.

Q And they also noted that at 24-month follow-up, rates of superficial and deep dyspareunia were low with no difference between the groups. Is that right?

A Right.
Q Another article that you considered in forming your opinions was an article, and I think you discussed this in your report. It's a systematic review and meta analysis by a Dr. Tommaselli and colleagues. Is that right?
A Right.
Q And this looked at only studies with a

follow-up of 36 months for transobturator midurethral slings and 60 months for retropubic midurethral slings. Is that right?
A Yes. Yes, it is.
Q That study spoke to the issue of chronic or persistent pain; correct?
A Correct.
Q Okay. And it indicated that persistent or chronic pain, which they defined as pain persisting beyond the perioperative period or reported at the last follow-up visit was reported by 13 patients for retropubic midurethral slings and 30 patients for transobturator midurethral slings. Is that right?
A Right.
Q So that's 13 retropubic patients out of 3,974?
A Right.
Q And 30 transobturator patients out of a total of 2,432?
A Right. Yes.

Q And is this one of the studies that you reviewed and relied on in forming your opinions regarding the safety and efficacy of the TVT and TVT-O devices?

A It was.

Q Another study that you -- did you also look at

a paper by an author named Schimpf and Colleagues?

A Yes.

Q And that was a systematic review and meta analysis as well?

A Yes.

Q And that was done by the Society of Gynecologic Surgeons' Systematic Review Group. Is that right?

A Yes.

Q And that study included a table that lists the summary estimate of incidence for various complications associated with not only retropubic and obturator midurethral slings made of synthetic polypropylene mesh, but also procedures involving -- or the pubovaginal sling procedure and Burch procedure. Is that true?

A Yes.

Q And does this Schimpf study, the systematic review and meta analysis suggest that chronic pain or dyspareunia are complications that are unique to midurethral sling surgeries?

A No, it does not.

Q And that's a study that you reviewed and relied

on in forming your opinions in this case?
A Yes, it was.
Q You were asked a question earlier about the

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antioxidants that are used in the TVT and TVT-O mesh. You mentioned one that was, I think it was DLTDP that you said?
A Yes.
Q And you said the other one started with an "S," but --
A Yeah. I just -- yeah, I couldn't bring it to the tip of my tongue.
Q Was Santonox the --
A Santonox. Exactly.
Q Santonox was the one you were thinking of?
A Yes, it was.
MR. JONES: Objection.
Q (By Mr. Koopmann) Do systematic reviews and meta analyses of the literature such as the Schimpf, and Tommaselli, and Ford reviews that we just looked at, did those suggest to you -- strike that.
Do those systematic reviews and meta analyses like the Schimpf, Tommaselli, Ford articles, shed any light on whether retention is taking place due to sling contraction?
A Yes, I believe they do. And it's clear that, in those studies, that there was very low rates of urinary retention with either retropubic or

transobturator slings.

Q The Schimpf study, for instance, indicates that retention lasting longer than six weeks post-operatively occurred with 2.4 percent of transobturator sling patients?

A Yes.

Q And what percentage of retropubic sling patients?

A 2.7 percent.

Q And in what percentage of patients receiving a pubovaginal sling?

A 7.5 percent.

Q And in what percentage of patients receiving a Burch procedure?

A 7.6 percent.

Q There was some discussion earlier of fraying of the mesh. And I think there was a discussion of whether, when it's removed, the ends can be frayed. Does that mean the ends that are removed -- the ends of the mesh from the removed specimen?

A Well, the removal of the specimen is in and of itself a distorting process. The removal of the mesh can't occur without significant pressure and tension on the material that is being removed. And the material that is -- when it is removed, again, it becomes terribly distorted, but at the time of

dissection it's easy enough to see that this material is lying quite properly and is easy -- I mean, when you do a portion of that dissection, you see a very nicely laid-in piece of prolene mesh.

But, again, our process is to remove the fibrotic capsule that exists within the mesh and to extract it, and in doing so, the mesh becomes, of course, badly distorted.

Q The mesh that you've removed?

A Yes. The mesh, once removed, it is, again, very distorted.

Q In your experience, does the mesh that remains in the patient, albeit having had a piece removed, does that become badly distorted?

A No. No. The focus, again, on exposed mesh is to remove as little of that as possible. We know that once that exposure occurs that there is no alternative to removal of the exposed mesh and re-approximation of tissue. Once re-approximated it will heal over that area. But without the removal of that, oftentimes, very small segment of mesh, it does not heal effectively.

Q Is it commonly known among pelvic floor surgeons, that if a mesh exposure occurs, that the woman's partner could feel that exposure during

sexual intercourse?
A I suspect that that can occur sometimes. I don't know to what -- yeah. Again, it certainly can occur and does occur.
Q And do you think that's something that is commonly known among pelvic floor surgeons?
A Oh, I believe it is.
Q Can Burch sutures be placed too tightly causing urinary retention?
A Absolutely.
Q Can fascia lata slings or rectus fascia slings be placed too tightly causing retention?
A Yes.
Q You were asked some questions about the reliance list earlier, and you said you didn't personally prepare that reliance list. Is that fair to say?
A Yes. I didn't type it.
Q The reliance list at the front indicates that it incorporates the articles that you've referenced in your report?
A Right.
Q You were asked some questions about the Ward/ Hilton five-year follow-up study. Do you recall that?

A Yes.
Q And you were asked some questions about Ethicon's involvement in that study. Do you

remember those questions?
A Yes.
Q One of the things that the authors noted was that the investigators had complete freedom to analyze the data and report the results as they saw fit. Is that right?
A Yes.
Q Even if Plaintiff's counsel showed you an article of a low-level case report, or series, or other study that suggested that there was roping, or curling, or fraying, or particle loss of the mesh; would that change your opinions whether those things are not clinically significant?
A No.
Q And why is that?
A Well, because we see such good results with our patients. You know, particle loss, honestly, is almost silly to talk about when you think of all of the different surgeries that we do intra-abdominally and within the pelvis where small pieces of either the end of a very small needle or clips that are applied internally. It's silly to not understand

and expect that the normal physiologic process of encapsulation and protection of the body does not occur with those in the same way that it does with the midurethral sling. And so at least the particle loss is something that, honestly, is just a silly

debate because every one of the physicians who have suggested that has gone through medical school, they know human physiology, and should truly consider that.

The issue of roping, fraying, curling, I don't -- I don't know that that doesn't occur, but if it does, it has effectively no clinical significance for my patients.

Q And is that based on your review of the -- well, it's based on your clinical experience, in part?

A Yes.

Q Is it also based on those systematic reviews and meta analyses?

A Yes.

Q Do physicians in your experience use the terms "erosion" and "exposure" and "extrusion" interchangeably?

A They do. They do.

Q And when the Instructions For Use warns that

there can be an extrusion or erosion, does that tell a surgeon that the mesh can become exposed within the vagina?

A It does. It does. We all know that there are definitions, very clear definitions for these things, but we're just lazy enough to continue to use exposure, or extrusion, or whatever, interchangeably. And we talk about them in that way

without specific -- without adherence to the very specific definitions that have been provided.

Q Can a wound dehiscence occur in connection with any surgery?

A Yes, it can.

Q And that's when a surgical incision that's been closed reopens?

A Correct.

Q And can it happen in a midurethral sling surgery?

A It can.

Q And so the midurethral incision through which the sling is implanted can dehisce or open revealing the sling underneath?

A It can.

Q And is that commonly known knowledge among pelvic floor surgeons?

A Absolutely.

Q Is frequency of complications associated with anti-incontinence procedures reported in the peer-reviewed published medical literature; frequency of complications?

A Is that reported?

Q Yes. In the medical literature, like the Schimpf study we just saw.

A Yes. Yes, it is.

Q And does that frequency vary from study to

study?
A Yes, it does.
Q And is that part of the reason why systematic reviews and meta analyses are helpful because it encapsulates all of the various studies out there to try to take a look at what the true incidence is?
A Yes.
Q And is it your opinion, because the frequency with which complications occur is ever-changing and reported in the medical literature, that that does not need to be included in the IFU?
A No, I don't believe that it does.
Q No, you don't believe that it does need to be included in the IFU?
A Correct. I don't believe it needs to be

included in the IFU.
Q Even if studies don't have pain or dyspareunia or any other complication listed as the primary end point of the study, do those studies nonetheless track pain and dyspareunia and other complications and report on them?
MR. JONES: Object.
A I think they typically do.
MR. KOOPMANN: Those are the questions I have for you, Dr. Fiegen. Mr. Jones may have some follow-ups.
EXAMINATION BY MR. JONES:
Q Okay. Doctor, rapid-fire action here.

Encapsulation is part of the normal physiological healing process in every patient; correct?
A Every patient that has an intact immune system.
Q Okay. And when you remove mesh there is a fibrotic capsule on the mesh; correct?
A Correct.
Q And of the 2,400 patients that you have implanted the sling in, are you aware of the percentage of those patients who have filed a lawsuit alleging that the implant they received was defective?
A No. I am not aware.

Q Okay. And of those 2,400 patients, are you aware of the percentage of those patients who currently suffer from urinary retention?
A Well, I believe I am aware.
Q Okay. What is the percentage?
A Of patients experiencing urinary retention?
Q Yeah. Of your 2,400 --
A Yeah.
Q -- patients that --
A Yeah.
Q -- you have implanted a sling in, what percentage of those patients currently, today, suffer from urinary retention?
A I don't think any of them do, Nate. We treat that. If we have to, we go back to the operating

room and release tension on the sling. We frequently will do urodynamic testing with those patients.

Almost all of them are tested to make certain that we haven't missed a potential bladder atony that may be developing or may have occurred, and make certain that release of the sling is very likely to improve that patient's retention. But we just don't leave them sitting.

Q I get it. Of those 2,400 patients that you've

implanted the sling in, are you currently aware of the percentage of those patients who report vaginal pain today?

A When they report vaginal pain to us, we address that issue in many different ways, either medically with analgesics, with physical therapy, with trigger point injections. And if their pain does persist, and we believe that it is entirely related to the effects of the surgery and the presence of the midurethral sling, we simply go ahead and discuss with them the option of a removal. And many of our patients who have reported some persistent pain at pain levels of 2 or 3, they would much rather deal with that and use occasional analgesics than to return to a life of urinary incontinence.

Q Okay. And you kind of answered the question but you kind of didn't, so I have to ask it again.

A All right.

Q Of the 2,400 patients that you've implanted a sling in, are you aware of the percentage of those 2,400 women who currently suffer from vaginal pain?
A No, I'm not aware of that percentage. My hope is that it's zero percent that continue to have pain. We only know if they return, and we have a very good follow-up with our patients. And I'm not

sure if it's the nature of our clinic, if it's our preoperative indoctrination or if it's just the patients themselves who continue to follow up. I maybe should include the approach that we take. Any patient who undergoes surgery through our office will ultimately be contacted within 24 hours after their surgery. They are seen within one week. If we do not see that patient in follow-up within that first week, our office is calling that patient, trying to locate them.

And, again, we work very hard in our office to maintain effective follow-up of our patients so that we know if issues are arising, and if there are late complications we -- again, our hope is that they'll return to our office.

Q And of the 2,400 women that you've implanted a sling in, do you know how many of those patients currently suffer from recurrence of their stress urinary incontinence?
A I don't. Yeah. I don't know that number, I'm

afraid. I'm sorry. I don't. It's a very small number, but I can't tell you specifically. I believe it would be less than 1 percent.

MR. JONES: Those are all the questions I have. Thanks again, Doctor.

THE WITNESS: You bet.

EXAMINATION BY MR. KOOPMANN:

Q Just one follow-up question, Dr. Fiegen. When you mentioned the existence of a fibrotic capsule occurring around the mesh, are you saying that the mesh is encapsulated without tissue incorporation occurring?

A No, no. That the sling is incorporated with fibrotic tissue, collagen, macro fascias, blood vessels. It penetrates the sling and fills the sling pores. What we remove is the capsule. We don't remove the internal fibrous tissue that is a part of that encapsulation.

MR. KOOPMANN: Those are all the questions I have. All done, Nate? Nate, are you still there?

MR. JONES: Sorry. All done. Thank you. Thanks, Pat. Thank you, Doctor.

MR. KOOPMANN: Thanks, Nate. Bye now.

(Witness excused.)

Pat L. Beck, Court Reporter
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STATE OF SOUTH DAKOTA)
:SS CERTIFICATE
COUNTY OF LINCOLN)

I, Pat L. Beck, Registered Merit Reporter and Notary Public within and for the State of South Dakota:

DO HEREBY CERTIFY that the witness was first duly sworn by me to testify to the truth, the whole truth, and nothing but the truth relative to the matter under consideration, and that the foregoing pages 1-137, inclusive, are a true and correct transcript of my stenotype notes made during the time of the taking of the deposition of this witness.

I FURTHER CERTIFY that I am not an attorney for, nor related to the parties to this action, and that I am in no way interested in the outcome of this action.

In testimony whereof, I have hereto set my hand and official seal this 22nd day of March, 2017.

_____

Pat L. Beck, Notary Public
Expiration Date: June 11, 2017
Iowa CSR: No. 1185

Pat L. Beck, Court Reporter
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ERRATA SHEET

Pursuant to the Rules of Civil Procedure, I have read the foregoing pages 1-137, inclusive, and have noted any and all changes in form or substance desired in my testimony, and have signed below on the _____ day of _____, 2017.

PAGE & LINE	CHANGE IN ANSWER	REASON FOR CHANGE

_____
Michael Fiegen, M.D.

_____
Notary Public

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